EXHIBIT 2K

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO PLAINTIFFS:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Diane Bellew (2:12-cv-22473)	

RULE 26 EXPERT REPORT OF PROF. DR. MED. UWE KLINGE

I. BACKGROUND AND QUALIFICATIONS

With regard to my medical training, I attended medical school in Aachen, Germany from 1977 to 1983. I began my medical profession at the surgical department of the University Hospital of the RWTH, Aachen, Germany (Department heads/Mentors: Prof. Reifferscheid - 1985, Schumpelick 1985-2010, Neumann 2010). From 1995 to 2006, my practice was focused primarily on abdominal surgery, and specifically, hernia repair. As a hernia surgeon, I used textile implants (flat meshes) for the repair of abdominal wall hernia or defects in more than 300 patients mainly groin hernia, umbilical hernia, incisional hernia and parastomal hernia. Although I never performed surgery for repair of SUI or POP, I implanted and studied the mesh used in TVT, Prolene, extensively.

In 1993, in addition to my surgical practice, I began focusing on surgical research in the area of biomaterial science including tissue engineering, material characteristics and designed preclinical models for surgical mesh and histopathology. I am the author/co-author of approximately 200 peer-reviewed publications listed in PubMed, over 100 of which involve hernia and/or surgical mesh. I have authored and/or contributed to more than 50 book chapters and have been an invited lecturer to more than 160 speaking engagements/conferences. I have received numerous research grants from various institutions and corporations including several grants from the German Ministry for Education and Research, the Ministry for Economics, the German research foundation DFG, the NRW Ministry for Education and Research, the Interdisciplinary Center for Clinical Research of the University (RWTH), as well as from industry (Ethicon, Covidien). (Attached hereto as Exhibit "A" is a current copy of my Curriculum Vitae with a list of my publications).

In 1994, we began looking at soft tissues and at the time, there was no information to help understand the cellular response to these materials. I then started to work with Dr. Bernd Klosterhalfen and together, we established a way to analysis soft tissue reactions in order to determine the difference between good materials and the best materials. This lead to the ability to see the extent of inflammation, foreign body reaction and fibrosis a biomaterial will have on the soft tissue and how that will directly relate to numerous complications. After the method was established, it was found in many of our publications and in the publications of our peers.

II. BRIEF HISTORY OF TEXTILE MESHES FOR TISSUE REPAIR 1958-1993 – THE ABDOMINAL WALL

The current use of textile implants, so-called meshes, is based on Usher who, in 1958, started to publish the successful reinforcement of abdominal wall in six dogs. Initially, meshes were regarded an alternative procedure, particularly in big hernias. In 1986, Lichtenstein presented his procedure of mesh implantation as the new standard for groin hernia repair. With this technique, the mesh reinforces the tissue in a so-called "tension free" manner. In the early years, Usher used a knitted structure of polypropylene, later on widely known as Marlex®. However, Marlex® had increased stiffness after implantation along with considerable complications. Alternatives to Marlex were the polyester mesh Mersilene® or the ePTFE from Gore.

In the late 1980's and early 1990's, when polypropylene surgical mesh was starting to be used in hernia surgeries, there was a general lack of knowledge about the materials and about the clinical outcomes associated with these materials. Side effects often manifested with a considerable delay of up to several years. Correspondingly, reports dealing with pain as a major postoperative complication (less than 10% of all hernia publications in PubMed) were published with a delay of years [Fig.1]. We began to look at the scar formation pathologically and developed the theory that incisional hernias could be due to a biological problem.

III. DEVELOPMENT OF THE FIRST LARGE PORE MESH CONSTRUCTION THAT WAS ADAPTED TO PHYSIOLOGICAL REQUIREMENTS

In the early 1990's, we speculated that an adaptation of the strength of surgical meshes to the physiological requirements of the tissues in which they would be implanted may allow a considerable material reduction which could improve biocompatibility. We felt that the textile characterization of meshes at that time did not sufficiently reflect the physicochemical properties of the textile, so we had to start almost from the beginning to first identify the relevant parameters.

RWTH University initiated a research program such that in conjunction with various grants, we could add some basic investigations to this project. Through cooperative efforts with Ethicon and the support by these research grants, the project went on for about 10 years. In this period, we gained significant knowledge about the textiles; we defined standard biomechanical characterization for better comparison; we established models for testing the tissue response in animals; we looked for parameters that reflected the inflammatory and fibrotic activity of the foreign body reaction; we developed a technique to quantify the biomechanical impact on, and the biomechanical properties of, tissues.

As our research progressed, we calculated that hernia meshes needed a tensile strength of 16 N/cm and an elasticity of about 20-30% at this strain [Fig. 2]. Ethicon provided our research team with thin (about 40 µm) polypropylene threads. Because we were provided only with these 40-µm fibers, we had to combine 5 strands of them at interval distances of 2-3 mm to withstand a strain of 16 N/cm. As this polypropylene net was very floppy, we added an absorbable fiber of Vicryl® (Ethicon) to temporarily make it stiffer. After absorption of the Vicryl®, there would remain just an open structure, with about 30% of the material of the Marlex®. This new structure with pores larger than 2 mm, later marketed as Vypro® by Ethicon (1998), was then studied extensively in several experimental studies. The results were presented at several conferences and most of it has been published in PubMed-listed journals.

In the 1990's, the mesh proponents were convinced that the problem of recurrence had been solved, that the outcome was not affected by the type of material used and that mesh-related complications were essentially nonexistent but occurred mainly as a result of surgical technique or patient co-morbidities. However, our extensive surgical mesh research over twenty-years, including our research, with Ethicon, demonstrates that these opinions are incorrect.

IV. BIOMECHANICS

The main task of biomaterials used for surgical repair is to strengthen the tissue in which it is implanted and to restore its function. Specific to pelvic organ prolapse, the primary task of the prosthetic is to strengthen the pelvic floor tissues and to restore the pelvic anatomy and function. The mesh should mimic as closely as possible, and be integrated physiologically into, the tissues of the pelvic floor based on a maximum biocompatibility. Such surgical biomaterials should be without serious long-term complications such as recurrence, erosion, infection or chronic pain, and should have optimal handling characteristics for an easy, comfortable and safe repairs.

Ethicon's professional education team communicated what it considered to be the "ideal" mesh requirements for pelvic floor repair to physicians that were being trained by Ethicon in the Prolift technique. They stated to physicians that the "ideal" vaginal graft should "be histologically well tolerated (inert), resist infection, be easily handled and implanted, incorporate into surrounding tissues, resist mechanical stretch, not shrink, and recreate and maintain the physical characteristics of the supple and distensible vaginal wall." ¹

Ethicon aware of the difficulties in defining the biomechanical requirements of the human pelvis. They admit in their internal documents regarding the biomechanical requirements of the pelvis that although "...the ideal mesh for prolapse repair which mimics precisely the biomechanical needs of the pelvic floor region has not been developed."

Ethicon recognizes that:

"...a recent major focus of mesh development and research is the patient's quality of life. Pain and discomfort can result from stiff mesh that were

¹ ETH.MESH.00033325: Professional Education PowerPoint presentation titled "The Science of Augmented Extracorporeal Reconstructive Pelvic Surgery" in which the "Ideal Mesh" is described

² ETH.MESH.03906525 Graft or No Graft PowerPoint Presentation

originally designed for hernia surgery and 'over-engineered' to exceed the burst strength of the abdominal wall at the cost of losing compliance. Although limited data suggests that, in terms of anatomical and biomechanical outcomes, synthetic polypropylene meshes are superior to biologic meshes, there is significant evidence that the complications associated with synthetic meshes can cause significant morbidity including infection, erosion, exposure, and pain. In addition, the vaginal tissue to be augmented is often structurally compromised, atrophic, and devascularized. Such poor tissue quality increased the risk of poor tissue incorporation into the mesh potentially resulting in suboptimal healing and mesh exposure or erosion into an adjacent viscous. Moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina compliance. Research has demonstrated that bioprosthetic mesh implantation results in a scarring reaction and subsequent decreased compliance. An ideal quality of prosthetic mesh would be to mimic the compliance of the supported tissue thereby resulting in more comfort and function after implantation. To be able to define the most appropriate design parameters for the next generation of pelvic floor prosthesis it is important to generate an advanced understanding of the pelvic floor biomechanics and associated mechanical boundary conditions."³

Ethicon scientists recognized that the unique requirements in pelvic reconstructive surgery include the fact that 1) anatomically, the pelvis has a complex, 3-dimensional architecture and vector forces with little or no bony (and often pelvic floor muscle) reinforcement, and 2) functionally, the prosthetic must remain pliable as a result of pelvic organ filling/emptying, tissue pliability, and sexual function.⁴ These and other Ethicon scientists also admitted that there is no descriptive model available to predict the mechanical behavior of pelvic mesh implants. Furthermore, Ethicon's Medical Affairs Director, Axel Arnaud, testified that Ethicon's claim that their pelvic floor meshes remain soft, supple and/or pliable was "an illusion".⁵

Other employees at Ethicon, namely, those involved in regulatory and sales and marketing, told a different story. In the Prolene Soft 510(k), the Gynemesh PS 510(k), as well as in the Gynecare Prolift IFU, Ethicon claims that "the elastic properties of the mesh adapt to the various stresses encountered in the body." Ethicon admitted to the FDA in 2007 that they had no data to support this statement.⁶ In its patient brochures for Prolift, Ethicon claims that the Prolift repair system is "a revolutionary surgical technique... [that] uses a soft synthetic mesh specially designed for placement through the vagina..." However, the term "specifically designed" came to the attention of Mark Yale, WW Director of Risk Management during the development of the

³ ETH.MESH.02010834-ETH.MESH.02010854: February 16, 2011 report written by Jurgen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design"

⁴ ETH.MESH.00033325: Professional Education PowerPoint presentation titled "The Science of Augmented Extracorporeal Reconstructive Pelvic Surgery" in which the "Ideal Mesh" is described

⁵ Axel Arnaud Deposition November 15, 2013 68:10-69:13

⁶ ETH-65881: Gynecare Prolift IFU

⁷ ETH-00255: Ethicon Gynemesh PS 2006 marketing brochure

Prolift +M IFU. He stated that "this mesh was not 'specifically designed' for Prolift application, we pulled a mesh out of our existing bag of tricks."

Dr. David Robinson, Medical Affairs Director at Ethicon, gave a Power Point presentation titled "Review of Surgical Techniques Using Mesh" which was marked as Plaintiffs' Exhibit 519 of his deposition. The presentation states: "material science has been slow to meet the special requirements of the vaginal environment" and "The vagina is **NOT** the abdomen and it is not similar to any other surgical environment." When this portion of his presentation was discussed at deposition. Dr. Robinson agreed that these are accurate statements.

Physiologic properties of pelvic tissue

The primary difficulty in developing a model to predict the mechanical behavior of pelvic mesh implants lies in the understudied and poorly understood characteristics of vaginal tissue. Drawing conclusions from studies involving animal tissues in an attempt to correlate those findings to the tissues in the human pelvis has severe limitations. As Ethicon has recognized, "[a]nimal models allow for controlled studies, which are useful in understanding the underlying factors that may contribute to the development and progression of human diseases by systematically examining confounding risk factors. However, the need to translate findings to the clinic is very important, and therefore understanding how these animal models relate to humans must be evaluated." In fact, in the 2010 Preclinical Efficacy Assessment for Ethicon Gynecare Gynemesh M, it says, "There is no representative quadraped animal model of human vaginal prolapse." It then goes on to say that the most similar pelvic anatomy would be that of a baboon, but, "this species has not demonstrated the pathology of spontaneous pelvic organ prolapse" 12

At the conclusion of our work in the development of Vypro hernia mesh with Ethicon, my colleagues and I published an animal study in which we demonstrated that the physiological forces of the abdominal wall could be quantified. By properly defining these physiological forces for the first time, we were able to demonstrate how the animal model related to human in vivo behavior to improve the textile structure of hernia meshes, and thus, to improve the symmetrical distribution of the retaining forces in all directions. Compared with the considerable restriction of the abdominal wall mobility by Prolene (polypropylene) and Mersilene (polyester) meshes, there was no increase in the bending stiffness after the implantation of the new mesh in rodents. Histological examination showed a pronounced reduction of the inflammatory reaction in the tissues, and the collagen bundles were orientated merely around the mesh filaments instead of forming a scar plate that completely embedded the

⁸ ETH.MESH.00318775: Email dtd 5/08/08 from Mark Yale to Jennifer Paine, Jonathan Meek et al regarding Prolift mesh was "not specifically design".

⁹ ETH.MESH.00396836: PowerPoint presentation created by David Robinson titled "Review of Surgical Techniques using Mesh"

¹⁰ David Robinson Deposition Testimony from rough draft 293:13; 194:14

¹¹ ETH.MESH.02010834-ETH.MESH.02010854: February 16, 2011 report written by Jurgen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design"

¹² ETH.MESH.04940233 – Preclinical Efficacy Assessment for ETHICON GYNECARE GYNEMESH M

¹³ U. Klinge, et al., Modified Mesh for Hernia Repair that is Adapted to the Physiology of the Abdominal Wall; Eur J Surg 1998; 164: 951-960

mesh. By adapting the design of the new hernia mesh to the physiological forces of the abdominal wall, we were able to reduce the amount of prosthetic material which caused less inflammation and less restriction in the mobility of the abdominal wall while retaining the required tensile strength of 16 N/cm.

No similar, definitive studies have been conducted by Ethicon for the pelvic floor. Pelvic tissue is extremely complex; it has a non-linear stress-strain relationship, large deformation before yield, is viscoelastic, inhomogeneous, anisotropic and, when trying to analyze the tissues upon explant, has changing vaginal tissue properties after removal from the body. There have been a number of scientists and surgeons, Cosson, Rubod, Boukerrou, and Boulanger, just to mention a few, who have attempted through various studies to characterize the biomechanical behavior of human vaginal tissue. However, as is evidenced by their studies and acknowledged by Ethicon, "the reported vaginal tissue properties vary extremely for different investigators and different experimental setups; there is no consistent nomenclature for biomechanical properties established; and, the reported material parameters exhibit a strong deviation even between different patients, examined by the same investigators...more data is needed from humans to help us characterize the differences between normal and pathological tissues, as well as to help us identify appropriate animal models." 15,16

Ethicon R&D engineer, Christoph Vailhe testified that newer manuscripts contain more reliable and definitive data regarding vaginal tissue properties including elasticity. However, a review of those manuscripts indicates that they actually continue to demonstrate ongoing debate and a lack of reliable and sufficient data concerning vaginal tissue properties. ¹⁷ ¹⁸ ¹⁹

Christoph Vailhe further testified that "As of 2012, no validated animal model exists to evaluate mesh erosion in the pelvic floor or to determine the biomechanical forces of the pelvis".

Apparently Ethicon merely converted our work on new generation hernia meshes and repackaged it as pelvic meshes assuming, without justification, that a safe mesh design for hernia application equaled a safe mesh design for pelvic floor application. As injuries to numerous patients continue to mount, this assumption has proven dangerously faulty.

For example, from October through December 2008, prior to Ethicon's launch of its new generation POP mesh, Prolift +M, there were required readings by the sales and marketing force to educate them regarding certain aspects of pelvic floor meshes before detailing the product with surgeons. These were known as "Prolift +M Pre-readings". Jonathan Meek, the Prolift +M

¹⁴ ETH.MESH.03753245: PowerPoint presentation titled "Biomechanics (Pelvic Forces)"

¹⁵ ETH.MESH.02010834-ETH.MESH.02010854: February 16, 2011 report written by Jurgen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design

¹⁶ ETH.MESH.03753245: PowerPoint presentation titled "Biomechanics (Pelvic Forces)"

 $^{^{17}\,}$ Christoph Vailhe Deposition June 20, 2013 45:23-46:11

¹⁸ ETH.MESH.04005863: Yves Ozog, Theoretical and Experimental Evaluation of Implant Materials used in Pelvic Organ Prolapse Repair (Doctoral thesis in Medical Sciences 2001)

¹⁹ ETH.MESH.07191144: Stepan Janda, Biomechanics of the pelvic floor musculature (Thesis)

²⁰ Vailhe deposition 06/21/2013 251:11 to 252:15

team member in charge of sales and marketing, included in these readings the work that my colleagues and I had done ten years prior (reference above).

This leads me to a number of important observations: 1) Ethicon had not conducted their own studies on pelvic mesh that would have built upon the knowledge they had gained a decade prior in order to determine whether their pelvic floor meshes approximated the physiological forces in the pelvis; 2) four of the seven suggested articles were studies involving hernia meshes from the late 1990's and only two of the remaining studies involved vaginal tissue; and 3) Mr. Meek admitted in an email dated October 29, 2008 that "...up until recently, I was ignorant to the work carried out by the likes of Cobb, Klosterhalfen and Klinge to name a few as it was assumed that they [were] primarily researching Inguinal Hernia repair and it didn't translate to Pelvic Floor. As it turns out, the vast majority of their work is pre-clinical which mirrors the more recent work done by Cosson, Boulanger, Rubod et al. done for the Pelvis."

Mr. Meek's statement is actually only partly true. Yes, our work was to a large extent "preclinical" in order to better understand certain design parameters of hernia meshes. However, unfortunately, our work was not continued by Ethicon in its development of pelvic meshes in that they failed to define the physiological forces in the pelvis and thus to translate this to design consideration for pelvic meshes. The work by Cosson et al. is preliminary in this regard. As Ethicon's own documents point out, there are still many unknowns regarding how best to design pelvic floor meshes in light of the still undefined physiologic requirements of pelvic floor and in particular, vaginal tissues. As Mr. Meek points out later in his email, these studies from the late 1990's have a few key points. Two of these that he communicates to the sales force are that "PP is the best of a bad lot re integration and retraction and there is a need to develop grafts that mimic the human tissue mechanical properties... [and] the need for grafts with elastic properties to match [the hyperelastic properties of the vagina]."

Unfortunately, Mr. Meek was not the only Ethicon employee who was misguided in this analysis. In May 2007, while the Prolift +M team was recommending updates to the IFU, they also attempted to use our 1998 rat study to support claims in their IFU for Prolift +M. It was disingenuous, at best, and closer to misleading for Ethicon to use a ten-year-old hernia mesh study from the abdominal wall of rats to validate their claim that Prolift +M would "illicit a minimum to mild inflammatory reaction" and "thus incorporate the mesh into adjacent tissue."

They also used our study from 1998 to claim that "the bi-directional elastic property allows adaptation to various stresses encountered in the body." First of all, the mesh we used in our study was Vypro, which was a multifilament PP mesh designed for the abdominal wall. Additionally, Vypro's PP fibers were intertwined with an absorbable component, polyglactin-910. Finally, the mesh in our study was implanted in abdominal tissue, not pelvic tissue. This is quite different from the use of Prolift in the female pelvic.

In another unfortunate example of the internal confusion and disparity of knowledge regarding surgical mesh and specifically, the differences between the tissues of the abdomen versus the pelvis, is seen in an email by a top R&D scientist, Joerg Holste, when He stated in

 $^{^{21}}$ ETH.MESH.02207388: Email dtd 10/26/08 from Jonathan Meek to Julie Bird et al regarding Prolift + M Pre-Reading

March 2007, "My thinking is that a pelvic floor prolapse is clinically comparable to hernia development, because it is part of the abdominal wall."²²

Clearly, the scientific reality weighs in favor of Dr. Robinson's analysis much more so than Dr. Hoelste's. More recently, Dr. Daniel Elliott of the Mayo Clinical published an article stating two very obvious concerns that should have been raised: "The first concern this should have raised regarding using synthetic mesh in the vagina is that synthetic meshes are not a perfect solution for abdominal wall hernias. A tremendous amount of data in the general surgery literature details a long litany of mesh complications...The second question or concern that should have been raised and thoroughly studied prior to widespread industry acceptance of transvaginal mesh kits is that the vagina is not the abdominal wall."

I agree. I also agree with Ethicon's conclusions in its analysis just last year in 2011 regarding the biomechanical considerations for pelvic floor mesh design: "We have shown that currently there is an important need for animal models in pelvic floor research...Of course, we ultimately need to know what is happening in the human female...The development of knowledge to understand the mechanics of pelvic floor disorders is imperative; yet, we are only just beginning to determine the necessary criteria on which to base design for pelvic floor implants." This admission by Ethicon comes 11 years after putting Gynemesh PS on the market and 6 years after putting Prolift on the market as a "revolutionary" procedure. From the time of the launch of Prolift in 2005 until the present, Ethicon continues to lack sufficient knowledge regarding pelvic floor in vivo forces and has never adequately calculated or estimated such forces through appropriate testing. 22 25 26

Strength

Measurements of the tensile strength of human tissue indicate a maximum strength of about 20 N/cm before rupture. Estimates of maximum physiological abdominal wall tensile forces indicate a maximum of 16 N/cm for smaller defects and 32 N / cm for larger defects. These limitations should be provided in all directions and considered as the minimal limit of the force for subsequent tearing. Although testing of sufficient tensile strength in the pelvic floor has been understudied, one can assume that it would not exceed the tensile forces in the abdomen (16 N/cm).

The Gynemesh PS white paper similarly states that strength is an important property of synthetic meshes. It also states that "Although in vivo forces and exerted strains on pelvic floor repairs are difficult to quantify, it is unlikely that they are significantly different than those found in the abdomen. Synthetic meshes have been used for years in the repair of abdominal and

²² ETH.00078537: Email dtd 03/07/07 from Joerg Holste regarding Lightning 510(k) requirements, "POP is part of the abdominal wall"

²³ Elliott, D. CON: mesh in vaginal surgery: do the risks outweigh the benefits? Wolters Kluwer Health. 2012

²⁴ ETH.MESH.02010834-ETH.MESH.02010854: February 16, 2011 report written by Jurgen Trzewik and Christophe Vailhe titled "Biomechanical consideration for Pelvic floor mesh design"

²⁵ ETH.MES.01156032: Clinical Expert Report for Gynecare Prolift Pelvic Floor Repair System

²⁶ Christoph Vailhe deposition 45:23-46:11

inguinal hernias and have proven to be of adequate strength to provide tissue support in that region. In fact, many meshes may be over-engineered with respect to strength and mesh density and weight may be able to be significantly decreased. However, the extent of this decrease and the minimum mesh strength requirement for pelvic floor repair is not known."²⁷ It is not possible to design an appropriate surgical mesh if the surgical environment is not understood.

Holste reported in 2005 in an article "Are Meshes with Lightweight Construction Strong Enough?" that surgical mesh must provide sufficient biological strength to meet physiological requirements without being over engineered. He added a graph to his publication showing that the maximum tensile strength on the abdominal wall is 150mmHg. The graph demonstrates that Ethicon's hernia meshes Ultrapro, Prolene Soft and Prolene all have burst strengths that are far above the maximum needed strength in light of the maximum abdominal pressure (Ultrapro = 650 mmHg; Prolene Soft = 700 mmHg; Prolene = 1650 mmHg). Holste correctly notes that over-engineered meshes (i.e., those whose strength is far above the maximum requirements of the tissue in which it is implanted thus leaving excessive amounts of foreign material in the body) lead to stiffness, excessive scar plate formation and abdominal wall restriction, all of which in turn lead to complications of reduced patient comfort and chronic pain. However, in that same article, he states that these meshes "possess adequate strength to repair the abdominal wall." He has missed the point. The question is not whether the meshes have enough or adequate strength, the question for Holste and his employer, Ethicon, should have been (and continues to be even to this day) 'Do our meshes have more material and/or more strength than is required to accomplish the task of reinforcing the tissues in which they are implanted?'. His conclusions thus belie a proper analysis of the data that he seeks to present given that Prolene Soft is over four times stronger than the maximum tensile strength of the abdomen, and Prolene is over ten times the required strength. ²⁸

Gynemesh PS/Prolene Soft is over four times stronger than the maximum tensile strength of the abdomen, and Prolene is over ten times the required strength.²⁹ Again, the main task for reinforcement by textile structures is the compensation of any tensile strength. In the case of prolapse, it should retain the pelvic floor with its organs which means there will be tension by definition. Thus, declarations or claims by Ethicon that the Prolift Kit are "tension free" are untrue and defy scientific sense or even common sense. The bearing of forces by the textile area is much more complex and hardly possible to be calculated exactly for every part of the mesh.

However, as Cosson et al. 30 discovered, the vaginal tissue showed rupture at a strain of about 20 N/cm. Thus, any textile does not need to be stronger than this. Considering the low forces of the surgeon to place a sling or a mesh, the necessary strength probably is in the range of 2 to 10 N /cm with variations depending on the degree of prolapse and the patient and her anatomy. However, more precise measurements or estimations are still lacking.

ETH.MESH.02053630: Gynemesh PS "White Paper"
 ETH.MESH.02227224: PowerPoint Presentation dtd 05/09/08 titled MGPP Thunder Decision Meeting

²⁹ Holste J. Are meshes with lightweight construction strong enough? Int Surg. 2005;90:S10-S12

³⁰ Cosson M, Lambaudie E, Boukerrou M, Lobry P, Crépin G, Ego A. A biomechanical study of the strength of vaginal tissues. Results on 16 post-menopausal patients presenting with genital prolapse. Eur J Obstet Gynecol Reprod Biol. 2003 Feb 10;112(2):201-5.

Ethicon has indicated in its internal documents that a force of 12.0 lbf (53 N) is placed on the mesh arms of the Prolift during implantation and that the required forces to pull the mesh arms through the cannula to be 0.73 lbf (3.24 N). It has also stated in other documents that the tensile strength of the implant straps "shall exceed 2.3 kg-force" (23 N)³³

During the development of Project Thunder, it was noted by the design team that as of 2008, pelvic floor material was still over-engineered. "There is no patient-centric PF material!...we need less foreign body material and materials that correlate to measured female pelvic physiological characteristics" Ethicon's researchers, when developing Project Thunder, they admitted that their own "pelvic floor materials are still over-engineered." This would include the mesh in the Prolift.

Elasticity

As stated in their Gynemesh PS "White Paper", Ethicon knew the importance of a pelvic mesh that was stretchable in all directions due to the complex, dynamic, multi-axial, three dimensional nature of the pelvic region. "Designing a mesh First, it is important to consider rigidity / flexibility ... [this is] extremely important when considering the dynamic nature of the tissues surrounding the vagina wall. An ideal mesh would be multi-directionally stretchable, easily conforming to tissues in the region of the repair. This would reduce the amount of tension on the fixation sutures allowing the tissue to function normally."

Ethicon states that "Prolene Soft Mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body." ⁴

After Ethicon obtained FDA 510(k) clearance for Prolene Soft, Ethicon used the "bi-directional elasticity" language in its IFU. In 2002, when FDA cleared Gynemesh PS, the same language appeared in its IFU. In July 2007, seven years after Prolene Soft was cleared for marketing, the FDA learned that Ethicon had been selling Prolift kits for two and a half years without proper clearance. In response to Ethicon's subsequent submissions to FDA in an effort to obtain 510(k) clearance to market both Prolift and Prolift +M, the FDA reviewer, Dr. Jiyoung Dang, questioned a number of Ethicon's claims including its claims of bidirectional elasticity and that this property allows adaptation to various stresses encountered in the body.

Various Ethicon employees attempted to find any evidence they had to support these claims. Dr. Christophe Walther (Ethicon Germany) questioned what was meant by "bi-directional elastic properties" or "allows adaptation to physiological stresses" and asked who was responsible for

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³¹ ETH- 01754: FDA Letter stating necessary force for arm pull out

³² ETH.MESH.00906445: Email dtd 01/18/08 from Vincenza Zaddem to Bryan Lisa regarding 510(k) mesh data with strength

³³ ETH.MESH.01992236: "Form for Test Method Applicability/Suitability"

³⁴ ETH.MESH.02227224: PowerPoint Presentation dtd 05/09/08 titled MGPP Thunder Decision Meeting

³⁵ ETH.MESH.01405170: PowerPointe Presentation dtd 6/18/07 by Cliff Volpe & Peter Meier title "Exploratory Program 'Thunder'"

³⁶ ETH.MESH.02053630: Gynemesh PS "White Paper"

these statements. Vincenza Zaddem (Ethicon Engineer and Team Leader of Prolift +M) stated "the team felt justified to use the statement 'bi-directional elasticity and that this property allows adaptation to various stresses encountered in the body' because this is the same statement used in the IFUs for PROLENE Soft Mesh and GYNEMESH PS. "Since this is standard data collected for meshes, without verifying we assumed we had data for UP demonstrating it is elastic in both directions." (Emphasis added).³⁷ Apparently, Ethicon also "assumed" they had this data for the Prolift but, after searching, Ethicon employees were unable to find data to support their claims and thus, they informed FDA that they would not make this claim in the IFU for the Prolift.

Structural Stability with regard to Strength and Elasticity

The principle of "tension free" might be somewhat true for meshes places in the abdominal wall, the textile structures in the pelvic floor necessarily, and by definition, cannot be "tension free". Their fixation to ligaments indicates that their function has to consider resistance against tearing stress and to prevent prolapse of the tissue under mechanical strain. Thus, any claim by Ethicon that their pelvic meshes are "tension free" is false and misleading.³⁸

In general, the huge variety of the different settings for measuring stability, elasticity, or porosity that are applied by mesh manufacturers, hinders the direct comparison of the material properties. The elasticity is markedly less for Gynemesh PS Mesh®. During the manufacturing process the mesh used in the Prolift kit is laser cut off of a large piece of Gynemesh PS, the edges of the Prolift mesh are still frayed leaving the end of the filaments "barbed" with irregular, sharp edges. At very low strain, the Prolift arms show a considerable rolling in, sometimes referred to in Ethicon documents as "mesh curling", "roping", or "lack of stress-shielding". Notably, even after relaxation of the arms after strain, the "curling" of the arms persists indicating a plastic deformation of the structure. The failure of the structure to return to its original or near original shape is known as "lack of memory". The frayed edges, "roping" and "curling" under minimal strain, excessive elasticity leading to pore deformation under strain, and lack of memory after strain, all are design failures that cause Prolift to have an unsafe design that unreasonably increases the risk of injury to patients in whom it is implanted. During testing that Ethicon performed in 2000, they claimed that under 2 pounds of force, Prolene Soft mesh does not curl. ³⁹ I've determined in my work with Prof. Muhl that this is not the case. In fact, Ethicon Medical Affairs Director, Piet Hinoul listing mesh roping as a hazard for both mesh exposure and tissue damage in his 2013 Clinical Expert Report for Prolift +M. 40

V. BIOCOMPATIBILITY

Biocompatibility of long-term implantable medical devices can be defined as 'the ability of the device to perform its intended function, with the desired degree of incorporation in the host, without eliciting any undesirable local or systemic effects in that host'. More simply put,

³⁷ .MESH.021989933: Email datd 9/10/07 from Christoph Walther to Vincenza Zaddem regarding "Info needed for FDA – Lightning", in which Zaddem states they "assumed they had data for UP".

³⁸ ETH.MESH.00086463: September 3, 2009 Email from Piet Hinoul Re: Prosima take away messages

³⁹ ETH.MESH.02613708: Completion Report Design Verification for Soft Prolene Mesh/Mesh Curling

⁴⁰ ETH.MESH.08315779 – Piet Hinoul 2012 Prolift +M Clinical Expert Report

biocompatibility entails optimal cellular response and tissue ingrowth. Piet Hinoul, Ethicon Medical Affairs Director agrees in his deposition that it was important for Ethicon to develop a mesh construction that would ensure only the desired amount of fibrosis because "you would want to limit excessive fibrosis.⁴¹

Histopathological investigations have shown that the amount of fibrosis is directly related to the amount of the inflammatory, cellular foreign body reaction (FBR) induced at the biomaterial/host-tissue interface. This was the primary reason we directed out early mesh research to decreasing the surface area of the mesh materials in relation to the physiological biomechanical requirement to minimize the biomaterial/host-tissue interface area. This realization and design shift led to our development of what became known as "the lightweight, large pore meshes over the classical heavyweight, small pore mesh materials (like Marlex and Prolene) is now widely accepted. These large pore or "macroporous" meshes, defined as pore sizes of >1mm in all directions, after accounting for stretch and pore deformation, have a decreased surface area, and compared to classical mesh materials, they induce a reduced inflammatory reaction with a decreased amount of clinical complications.

Weyhe et al. did a comparison study of heavyweight versus lightweight meshes to evaluate whether weight and structure of PP meshes were independent determinant factors for tissue incorporation of the implant. Their conclusion was that there can be worse biocompatibility of lightweight meshes compared with heavyweight meshes, if the lightweight mesh has very small pores. "Thus, the amount of implanted mesh was not the main independent determinant of biocompatibility (expressed as successful incorporation and diminished foreign body reaction) but the size of the pores."⁴² As between "lightweight" or "large pore", large pore was considered by far the most important design construct for maximum biocompatibility and thus a potential deterrent to mesh-related complications.

Not surprisingly, attempts to objectify the weight parameters or values for the best "lightweight" design were inconclusive and/or varied. A review of the scientific literature indicates that there has been no real consensus as to the categorization or definition of the weight limits by class. ^{43,44,45,46,47,48,49} In numerous documents in which they communicated their mesh

⁴¹ Piet Hinoul Deposition 540:1-10; 544:6-17; 545:5-13; 574:25-575:18

⁴² Weyhe D, Schmitz I, Belyaev O, Grabs R, Muller K, Uhl W, Zumtobel V. Experimental Comparison of Monofile Light and Heave Polypropylene Meshes: Less Weight Does not Mean Less Biological Response. World J Surg. 2006 Aug;30(8):1586-91

⁴³ ETH-47802: Cobb WS, Burns JM, Peindl RD, Carbonell AM, Matthews BD, Kercher KW, Heniford BT Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model..J Surg Res. 2006 Nov;136(1):1-7. Epub 2006 Sep 22.

⁴⁴ Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7

⁴⁵ Weyhe D, Belyaev O, Buettner G, Mros K, Mueller C, Muerer K, Papapostolou G, Uhl W. In Vitro Comparison of Three Different Mesh Contructions. ANZ J. Surg. 2008; 78:55-60

⁴⁶ Deeken C, Abdo M, Frisella M, Matthews B. Physicomechanical evaluation of absorbable and nonabsorbable barrier composite meshes for laparoscopic ventral hernia repair. Surg Endosc. 2011; 25:1541-1552

⁴⁷ ETH.MESH.0081180: Prolift characteristics

⁴⁸ ETH.MEH.02212840: Mesh Structures chart

weight classification to FDA, surgeons and patients, Ethicon stated that Prolene Soft/Gynemesh PS/Prolift were "lightweight". However, according to Cobb and Weyhe, at least, Ethicon's PS mesh was "medium weight", whereas Vypro, Ultrapro and Prolift+M would be considered "lightweight". The deposition testimony of an Ethicon Key Opinion Leader employee also reveals Ethicon's lack of understanding as to what constitutes "lightweight". In 2008, Vince Lucente, a urogynecologist who was the number 1 promoter of Prolift and Prolift +M, referred to Gynemesh as a "middle weight mesh". ⁵²

Therefore, to try to overcome some of these inconsistencies and hurdles, and to try to provide valuable guidance to surgeons who are considering whether to implant a mesh and if so, which ones, we set out to create a new classification of hernia meshes. Rather than using weight as the defining parameter, we contacted major manufacturers of meshes in and collected the physicochemical data of their products with the goal of deriving a classification system that grouped meshes according to their biocompatibility.

As we stated in our published article⁵³, it is important to note that even if a hernia mesh is considered "large pore" based upon the above classification, in order to avoid "fibrotic bridging" (discussed below), even large pore meshes must have a sufficient amount of "good pores" (>1mm in diameter, after stretch) in order to resist this consequence of the inflammatory process.

Foreign Body Reaction

All experimental and clinical studies indicate that mesh products on the market today cause an initial and chronic inflammatory tissue response in the recipient after implantation. The quality of the inflammatory reaction to foreign bodies of different natures is surprisingly constant, characterized by a rapid accumulation of huge numbers of phagocytic cells, in particular, blood monocytes and tissue-derived macrophages. This type of inflammatory process is known as a foreign body reaction (FBR). It is characterized by an initial inflammatory burst caused by a release of a huge cocktail of potent inflammatory mediators which then attract other cell types including T-cells, polymorphonuclear granulocytes (PMNs), plasma cells and fibrocytes. Within a few days, this cellular activity forms an early granuloma layer recognized by the very typical foreign body giant cells and an outer layer of fibrosis with deposition of collagen. This late stage granuloma is not a static type of chronic inflammation but rather, it represents a chronic wound with an increased cell turnover even years after implantation. Monocytes and tissue-derived macrophages, at the interface and in contact with the polymer, undergo apoptotic cell death and are replaced. [Fig. 6]

We published our results in 1998 and 1999 of the histological analyses from explanted mesh from rats, dogs and humans. The tissue response in humans was almost identical to the morphological observations in the animal models. In our 1999 study, we reviewed approximately

⁴⁹ ETH.MESH.02227368: Meshes/Devices Chart

⁵⁰ ETH.MESH.04037392: Prolift+M Sales Training Program PowerPoint Presentation

⁵¹ Axel Arnaud Deposition: 375:3-376:6

⁵² ETH.MESH.0067363: Vince Lucente webinar transcript

⁵³ Klinge U, Klosterhalfen B. Modified Classification of surgical meshes for hernia repair based on the analyses of 1000 explanted meshes. Hernia. 2012: 1-8

350 human explant samples of various mesh modifications gathered from centers all over Europe. Even 15 years after explantation, the longest observation in our study, a persistent chronic FBR could still be detected, indicating that mesh is likely never completely inert with respect to local inflammatory processes. The persistence of this FBR is important, especially in younger patients in whom the mesh will remain for several decades. The delay before explantation of mesh for infection of up to 56 months, for chronic pain of up to 48 months and for recurrence of up to 180 months established that in many clinical studies with shorter surveys of less than 1-2 years, the morbidity rates are underestimated. 54,55

Fibrotic Reaction

PP filaments cause an intense inflammatory response in the abdominal wall as well as the tissues of the pelvic floor. There is increased fibrotic reaction which stimulates remodeling at the tissue/implant interface. This intense scar formation contributes to the wound contraction. ⁵⁶

Fibrotic Bridging

In our studies from the late 1990's, in which we evaluated the inflammatory response and fibrotic reaction in the tissues at the interface with the mesh implant, we saw that that large pore mesh (Vypro) was integrated into a loose network of perifilamentous fibrosis with fat tissue present in between the fibers. In contrast, the small pore mesh was incorporated entirely in perifilamentary granulomas and scar tissue, which bridged the whole pore diameter <1 mm. This phenomenon, known as "fibrotic bridging" exists when granulomas, side by side, form a common outer fibrotic capsule joining each mesh fiber and forming a rigid "scar plate" covering the whole mesh. This scar plate leaves no space for further tissue ingrowth and leads to a number of complications including loss of elasticity and pain associated with the rigidity, shrinkage or contraction of the mesh, mesh erosion, nerve entrapment, bacterial encasement, chronic pain and dyspareunia, if used in pelvic floor repair.

With the development of Vypro, the first truly large pore mesh, we were able to increase the pore size by up to 500-600% (Vypro 3-5 mm vs. Prolene <1mm). Given that the risk of bridging fibrosis is increased by mesh with pore size < 1mm in all directions, any mesh designed with pores this small increases the risk of injury to the patient and is a less safe design than mesh with pore sizes > 1mm in all directions. Simply put: the greater the pore size or open space in between fibers, the less the risk of fibrotic bridging and formation of a rigid and potentially dangerous scar plate encapsulating the mesh. Ethicon had this information beginning in 1998.

⁵⁴ Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998: 164; 965-969

⁵⁵ Klinge U, Klosterhalfen B, Muller M, Schumpelick V. Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias

⁵⁶ Steinau, G., U.Klinge, A.Tittel, H.Skopnik, V.Schumpelick (1992) Gallenblasensteine im Kindes- und Jugendalter. Akt. Chir. 27:267-9

Effective Porosity

In approximately 2005, I applied for and received a grant to study the porosity of textile meshes in an attempt to objectify porosity in a reproducible manner. I contacted an engineer at the FH Aachen University of Applied Sciences, Thomas Muhl, and we embarked on a two-year project to create a porosity image analysis system that better characterized the pore geometry of meshes, both before and after strain. The results of this granted project were published in 2007 in the Journal of Biomedical Materials Research Part B: Applied Biomaterials. 57

Our research was based on my previous work from the late 1990's that pore sizes that prevent fibrotic bridging and will permit tissue ingrowth should exceed 1 mm between two PP filaments. As stated in our publication, "To exclude large pore areas that may be provided by long and thin pores with narrow parts of pores, the pore geometry has to be evaluated as well. Therefore, only those pores and those parts of the pores are extracted, which have dimensions greater than 1mm or 1000 µm in all directions. The remaining porosity is defined as 'effective porosity'.

In connection with this litigation, Prof. Muhl performed testing on Ethicon's surgical mesh product [Prolift/TVT Products) using the same protocol as we used in our study in 2007 and as reported again in 2013. 58 59 (NOTE: An Ethicon R&D Scientist, Vincenza Zaddem, Team Leader of Prolift +M and Technical Lead of Prolift, was shown the Muhl study from 2007 and she testified that it sounded like a valid test and that she believed that it would be a good test for Ethicon to look into in order to determine the effective porosity and effective porosity under strain of their pelvic meshes. 60 This was again confirmed in sworn testimony by Ethicon employee, Joerg Holste and circulated numerous times within Ethicon as a "more sophisticated set up" than Ethicon's method of porosity testing. 61 6263 Ethicon was also aware of the concept of "effective porosity" and the necessity of maintaining pore sizes of >1mm after stretch. 64 65 66

The significance of the Muhl method of testing these mesh products is that it provides useful data in terms of how the mesh, and different parts of the mesh, will perform in the human body. The first most important observation from this testing was that the effective porosity and the effective porosity under strain in Prolift produced less than optimal results. As minimal strain was applied to the test sample, the geometric shape of the pores deformed and ultimately collapsed. This deformation led to extremely small pores which would make the mesh highly

⁵⁷ Muhl T, Binnebosel M, Klinge U, Goedderz T. New Objective Measurement to Characterize the Porosity of Textile Implants. J Biomed Mater Res Part B: Appl Biomater. 2007; 84B:176-183

⁵⁸ Prof. Tomas Muhl Report

⁵⁹ J. Otto, et al., Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation of scar plates; J Biomed Mater Res A 2013 Apr 29 ⁶⁰ Vincenza Zaddem Deposition Testimony 387:14-20

⁶¹ Jorg Holste Deposition 417:9-418:22

⁶² ETH.MESH.02184130 2008 email circulating New Objective to Characterize the Porosity of Textile Implants

⁶³ ETH.MESH.04945136 2010 email circulating New Objective to Characterize the Porosity of Textile Implants

⁶⁴ ETH.MESH.03021946 T-Pro Stage Gate Meeting on August 25, 2008

⁶⁵ ETH.MESH.02587926: When the Implant Worries the Body

⁶⁶ ETH.MESH.017525352: Mesh Design Argumentation Issues

susceptible to fibrotic bridging, encapsulation by a rigid scar plate and the array of potential complications that occur as a result of this inflammatory process.

Another significant observation during the porosity testing by Prof. Muhl was the "curling", sometimes referred to as "roping", that occurred in the mesh arms of the Prolift under minimal strain. We published an article in 2007 ⁶⁷ in which we showed the tissue reaction and fibrotic ingrowth of PP due to curling/roping of the mesh due to scar shrinkage after H&E staining. [Fig. 9] As strips of mesh begin to curl, they act similarly to small pore meshes in that the fibers become situated too close together enhancing the inflammatory response and leading to fibrotic bridging.

Yet another significant observation during the porosity testing by Prof. Muhl was the "fraying" at the edges of mesh which could be seen upon removal from the package but became markedly worse in the Prolift mesh sample at minimal strain. These frayed edges create an increased inflammatory process. When frayed edges occur in the curled arms, an even greater inflammatory process is created.

After being subjected to even minimal strain or tension, the arms in the Prolift not only curled, frayed and demonstrated deformation of the pores, they also failed to return to their original or near-original geometric shape and design. This phenomenon is known in material science as plastic deformation and is sometimes referred to as a lack of "memory".

A mesh device that is permanently implanted in human tissue and reacts to implantation and in vivo forces in the manner in which the Ethicon meshes performed during Prof. Muhl's testing increases the risk of injury to patients in which it is implanted and is a less safe design than products that better withstand these in vivo conditions and do not display these poor outcomes. The PVDF product is a safer design for all of the reasons stated above.

Mesh Contraction

Mesh contraction, also known as mesh shrinkage, retraction, bunching or wrinkling is a common phenomenon after mesh implantation which is closely related to fibrotic bridging. [Fig. 15] Mesh contraction can be defined by a reduction of the surface area of the original implanted mesh. The surface reduction is due not to shrinkage of the mesh fibers themselves but rather to a retraction of the fibrotic scar tissues around the mesh. Retraction of the scar is a physiologic reaction of maturing scar which is characterized by a constant water loss and, consequently, a subsequent surface area decrease to an average of 60% of the former wound region. It is known to take place in the first few weeks after implantation but can last as long as 12 months or more after surgery. The medical literature and Ethicon's own internal documents report that there is considerable mesh contraction of surgical meshes made of polypropylene. ^{68,69,70,71,72,73,74} In fact,

⁶⁷ Klinge U, Binneboesel M, Kuschel S, Scheussler B. Demands and properties of alloplastic implants for the treatment of stress urinary incontinence. Expert Rev. Med. Devices. 2007; 4(3):349-359

⁶⁸ ETH-47802: Cobb WS, Burns JM, Peindl RD, Carbonell AM, Matthews BD, Kercher KW, Heniford BT Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model...J Surg Res. 2006 Nov;136(1):1-7. Epub 2006 Sep 22.

⁶⁹ Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh iHernia Repair. Surgical Innovation. 2005; 12(1):T1-T7

the TVM group in 2006 advised Ethicon of the common occurance of retraction or shrinkage in the Prolift arms and in the distal portion of the mesh which then creates a "cord-like" mesh. This issue not only leads to poor coverage leading to recurrence, but will also increase the amount of foreign body reaction due to pore collapse. This phenomenon then leads to additional complications including: pain, dyspareunia, nerve entrapment, increased inflammation, urinary and fecal incontinence, urinary retention, blood vessel injury and others.

In February of 2007, Dr. Kerstin Spychaj, Ethicon R&D prepared a presentation entitled, "State of the knowledge in 'mesh shrinkage' – What do we know?" which she presented at an Ethicon Expert Meeting on February 23, 2007 at Ethicon's Norderstedt facility. Dr. Spychaj did a literature review and concluded that the "ideal mesh" in order to avoid shrinkage would be a lightweight material (partially absorbable) with a pore size > 1mm and mild but not excessive FBR and wound contraction with swift and adequate tissue growth. Not only had Ethicon determined that shrinkage was obviously critical to the quality of its mesh products, they knew it could cause "vaginal anatomic distortion which may eventually have a negative impact on sexual function." Furthermore, they knew "its treatment is difficult." Several other Ethicon employees and/pr consultants provided sworn testify regarding the issue of mesh shrinkage. 78,79,80,81

There is an email exchange date July 2004 regarding mesh contraction/shrinkage in which Axel Arnaud suggested adding "mesh shrinkage" as an additional adverse reaction in the Prolift IFU. Mesh shrinkage had not been included in the Gynemesh PS IFU. Sean O'Bryan, Ethicon Regulatory Affairs, stated that "If mesh shrinkage is a real issue, then we have an obligation to put it in." However, he also stated that if this new adverse reaction was added, Ethicon would also have to add it to the existing Gynemesh PS IFU as a modification. Reither mesh shrinkage nor mesh contraction was added to the original or the revised Prolift IFU, nor was it added to the Prolift+M IFU.

⁷⁰ Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7

⁷¹ Tunn R, Picot A, Marschke J, Gauruder-Burmester A, Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound Obstet Gynecol. 2007 Apr;29(4):449-52.

⁷² ETH.MESH.01192895: Velemir L, Amblard J, Fatton B, Savary D, Jacquetin B, Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study. Ultrasound Obstet Gynecol (2010)

⁷³ Letouzey V, Fritel X, Pierre F, Courtieu C, Marès P, de Tayrac R. Informing a patient about surgical treatment for pelvic organ prolapse. Gynecol Obstet Fertil. 2010 Apr;38(4):255-60.

⁷⁴ Vollebregt A, Troelstra A, van der Vaart C. Bacterial Colonisation of collagen-coated polypropylene vaginal mesh: Are additional intraoperative sterility procedures useful? Int Urogynecol J. 2009; 20:1345-1351

⁷⁵ ETH.MESH.01774758: December 2006 email regarding TVM Group mesh design input

⁷⁶ ETH.MESH.01218361-01218367: Dr. Kerstin Spychaj, State of the knowledge in "mesh shrinkage" – What do we know? 04/05/2007

⁷⁷ ETH.MESH.02992139: Lightning Clinical Strategy dtd 11/22/06

⁷⁸ David Robinson testimony 260:5-22

⁷⁹ Scott Ciarrocca testimony 2012-03-29 00, (Page 340:9 to 340:12)

⁸⁰ Aaron Kirkemo testimony 105:14-108:16

⁸¹ ETH.MESH.03924887: Meshes in Pelvic Floor Repair

⁸² ETH.MESH.02286052: Email dtd 1/13/05 from Sean O'Bryan to Scott Ciarrocca Re: IFU Prolift

Degradation83

Studies as early as the 1970's and 1980's demonstrated concern over the degradation/oxidation effects of polypropylene when used in the human body. 84,85 It was presumably due to such concerns that Ethicon adds anti-oxidative additives to its compound batches when formulating and extruding the PP resin – a process that has barely been revisited, retested or changed since the late 1960's. 86

More recently, there has been growing concern regarding the degradation of PP in prosthetic mesh implants. It is believed that oxidation of the mesh occurs as a result of the chemical structure of PP and the physiological conditions to which it is subjected. This leads to embrittlement of the material, impaired tissue mobility and eventually chronic pain. Costello, et al. reported in 2007 that certain by-products of the inflammatory process causes the PP to be more susceptible to the oxidative effects of the metabolites produced by phagocytic cells during the inflammatory response. They saw cracks and other surface degradations such as peeling of the PP fibers under Scanning Electron Microscopy (SEM).

Studies have demonstrated that PP is not biologically inert. Clave, et al. performed a comparative analysis of 100 pelvic mesh explants. The average period of removal was 790.6 days. Over 20% showed such degradation damage to the fibers. [Fig. 3] The article states that the lead author of the study had an educational position for Ethicon Europe. ⁸⁸ Other authors have also written about the degradative effects of PP in the human body. ^{89,90,91}

The clinical implications of a degraded, oxidized surface of PP mesh fibers in human tissue are not completely known. Such degradation, depending upon the severity, can lead to cracking and peeling of the fiber's surface creating an enhanced inflammatory tissue response due to the lack of a smooth surface coming into contact with the tissue. The mesh is not at rest after implantation. As a result of the inherent nature of the physiological forces and stresses being placed on the prosthetic after implantation, the mesh will move and stretch in an anisotropic

⁸³ Expert Reports of Vladimir Iakovlev & Howard Jordi

⁸⁴ Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951

⁸⁵ Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982; 17:1233-1246

⁸⁶ ETH.MESH.0228619: Prolene Resin Manufacturing Specifications

⁸⁷ Costello C, Bachman S, Grant S, Cleveland D, Loy T, Ramshaw B. Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient. Surgical Innovation. 2007; 14(3):168-176

⁸⁸ Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. J Biomed Mater Res B Appl Biomater. 2007 Oct;83(1):44-9

⁸⁹ Cozad MJ, Grant DA, Bachman SL, Grant DN, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene, polyethylene terephthalate, and expanded polytetrafluoroethylene composites: spectral and thermal analysis

⁹⁰ Costello CR, Bachman SL, Ramshaw BJ, Grant SA., Materials characterization of explanted polypropylene hernia meshes. J Biomed Mater Res B Appl Biomater. 2010 Aug;94(2):455-62;

⁹¹ Ostergard, D. Degradation, infection and heat effects of polypropylene mesh for pelvic implantation: what was known and when it was known. Int Urogynecol J. 2011; 22:771-774

manner in the tissue. This frayed surface can damage the tissue in which it is implanted leading to an increased host defense response at the tissue/implant interface.

Furthermore, the cracked and frayed fiber increases the surface area of the mesh. Increased surface area causes a more intense foreign body reaction and thus, a greater inflammatory/fibrotic response. Finally, bacteria are more likely to lodge in the cracked areas of the fiber surface in vivo thereby increasing the risk of infection which would also create a greater host defense response.

It is important to note that Ethicon hired an outside consulting firm, PA Consulting Group, to analyze its surgical mesh for the pelvic floor. In an extensive report, dated May 18, 2011, PA Consulting opined that "Polypropylene can suffer from degradation following implant…..a process which initiates after a few days post implantation in animal studies."

Numerous reasons are listed as possible causes of such degradation. In fact, one of the clinicians that PA Consulting interviewed when collecting data for the report "proposed that variability in the raw materials, and/or processing thereof, could be affecting the clinical performance and outcomes. He articulated his intention to investigate this hypothesis." A collection of "high resolution images of excised meshes clearly show physical degradation of polypropylene filaments." The report states that these images were collected from Prof. Klosterhalfen, but rather than include them in the report, PA Consulting says that the images are "on file". ⁹¹

Degradation of PP in the human body has been the subject of scientific journals for decades, including one of which was authored by an Ethicon consultant, and at least one internal study. Yet Ethicon claims to the FDA, surgeons and patients that the PP material in Gynemesh PS and thus, Prolift is not "subject to degradation or weakening by the action of tissue enzymes." Internal documents reveal that there was some recognition of not only the degradative effects of PP in surgical mesh but also that Ethicon's PVDF mesh, Pronova, was more elastic and demonstrated less degradation than PP.

Interestingly, in the May 2013 deposition of Daniel F. Burkley, MS, 'principal scientist' in Ethicon's analytical characterization department, Mr. Burkley testified that in his 34 years at Ethicon, he was "...only familiar with one study ever conducted by Ethicon regarding possible degradation of its polypropylene sutures or mesh. This was a dog study that involved Prolene suture and at least two other competitors and perhaps another suture...[that he believed] was started around 1985.." [and] "...I believe it was a cardiac [study]. Mr. Burkley testified that the

⁹¹ ETH.MESH.02589032: May 18, 2011 report titled "Investigating Mesh Erosion in Pelvic Floor Repair" completed by Johnson & Johnson's PA Consulting Group

⁹² C. Töns, B. Klosterhalfen, U. Klinge, C.J.Kirkpatrick, C. Mittermayer, V. Schumpelick (1993) Septischer Schock und multiples Organversagen in der chirurgischen Intensivmedizin. Langenbecks Arch Chir 378: 217-232

⁹³ In the United States District Court for The Southern District of West Virginia Charleston Division; In Re: Ethicon, Inc.: MDL No. 2327 Pelvic Repair System, Products Liability Litigation and Various Other Cross-Noticed Actions; May 22, 2013 30(B)(6) Deposition of Daniel F. Burkley, MS; pp 23 - 24.

Prolene suture showed degradation of the Prolene suture that was still progressing after seven years, whereas the PVDF suture showed no such degradation. ⁹⁴

In my opinion, it has been proven to a reasonable degree of scientific probability that surgical mesh made of PP and used in the pelvic tissues is not biologically inert and does in fact undergo degradation at the surface of the mesh fiber leading to an increased host inflammatory response. Therefore, Ethicon had a duty to test the potential degradative effects of the body's reaction to the PP mesh used in Prolift in order to determine whether the anti-oxidants that it has been using for some decades does, in fact, prevent surface cracking and peeling of the mesh fibers in the human tissue. According to their outside consulting group, they do not.

It was inappropriate, false and misleading for Ethicon to claim that their PP meshes were not subject to degradation. In fact, Piet Hinoul, Ethicon's WW Medical Director, in a 2009 presentation, stated that "[modern day meshes] are not biologically inert". 95

Fraying/Particle Loss

In 2000, surgeons advised Brigitte Hellhammer, an Ethicon employee, that Gynemesh surgical mesh "released particles that migrate through the vaginal wall causing pain during intercourse". In November of 2003, Marty Weisberg, who at the time was the Senior Medical Director of Gynecare, made a note to the TVT file indicating that there had been 58 complaints of mesh fraying since 2000. In that memo to file, he stated that "Fraying is inherent in the design and construction of the product. The mesh elongates in places; the mesh narrows in places; and small particles of Prolene might break off." Ethicon deemed elimination of particle loss as an important 'CTQ' (Critical to Quality).

In 2003, Pariente published a study in which he evaluated the amount of material shed by different suburethral slings under certain test conditions. Dr. Pariente's conclusion was that "the very high particle shedding for both Sparc (AMS) and TVT (Ethicon) may be of significant long term clinical concern in some quarters." TVT had the highest percentage loss of initial weight at 8.5%. Other authors have commented on the fraying phenomenon of Ethicon's TVT slings as well. 100

The Pariente article then prompted the French regulatory agency, AFNOR to seek additional information from Ethicon regarding the high amount of particle loss. Ethicon employee, Gene Kammerer believed that the method that AFNOR was requesting that they use in order to

⁹⁴ Daniel Burkley Deposition May 23, 2013 315:8-13

⁹⁵ ETH.MESH.01264260: Piet Hinoul 2009 Presentation

⁹⁶ ETH.MESH.03924887: Meshes in Pelvic Floor Repair

ETH.MESH.00541379: Memo to File dtd 11/18/03 from Martin Weisberg Re: Mesh Fraying for TVT Devices
 135. ETH.MESH.00301741: Email from Dan Lamont to Jacqueline Flatow dtd 11/21/05 Re:!!!!!GREAT NEWS
 FOR TVT LASER CUT MESH!!!!!

⁹⁹ ETH.MESH.01221055: Pariente J-L; An independent biomechanical evaluation of commercially available suburethral slings. Issues in Women's Health

suburethral slings. Issues in Women's Health Moalli P, Papas N, Menefee S, Albo M, Meyn L, Abramowitch D; Tensile properties of five commonly used mid-urethral slings relative to TVT. Int Urogynecol J (2008) 19:655-663

determine particle loss was unrealistic and too rigorous. ¹⁰² Kammerer also stated that particle loss "is most likely an aesthetic tissue". ¹⁰³ However, information regarding the impact of particle loss on foreign body reaction and its clinical outcomes cannot be determined. It is therefore inaccurate for him to state that there is no clinical outcome to this loss of particles.

Prof. Thomas Mang, previously discussed, investigated Prolift and Prolift+M to determine whether particulates were detectable before handling, after attempts to detach fixed particles by rubbing or ultrasound, as a consequence of trimming the mesh by 5 cm incisions, or as a consequence of dynamic strain. Fragments were detected at several points for Prolift and Prolift +M. Prof. Mang found that particulates were visible even before any handling of the products occurred; he also found that that fragments of polymer detached from the mesh during handling (e.g. shaking or rubbing the mesh). More probably than not, particulates of this nature will create a host defense response that includes the same series of cellular reactions as the main portion of the mesh. Also, more probably than not, particulates scattered throughout the pelvic tissue will create an inflammatory response of some magnitude; will increase the overall foreign body reaction and inflammatory response; will increase the amount of the fibrotic reaction; and will run the risk of migrating into other parts of the body.

VI. CLINICAL OUTCOMES/COMPLICATIONS

Poor design leads to poor outcomes. Failure of a mesh manufacturer to properly and thoroughly identify and consider the relationship between the risk of complications and its relationship to design characteristics can have drastic, dangerous and life-changing consequences for patients. Neither surgeons nor patients are charged with the responsibility of designing and testing surgical meshes in a safe manner or being apprised of the latest scientific knowledge regarding the relationship between reported complications and their relationship to potential product design defects; this burden and responsibility falls squarely, and justifiably, on the shoulders of the manufacturer. Likewise, it is the responsibility of the manufacturer, not the physician or the patient, to appropriately warn of the known or knowable safety risks that accompany a particular product.

When asked about complications related to Ethicon's pelvic meshes, Ethicon former Director of Medical Affairs, Dr. David Robinson testified at his deposition in this matter as follows: "So what we have to do is assure that our product, per se, meets the characteristics that we are describing it having." If designing a safer pelvic mesh product was not possible, Ethicon had an obligation not to market the product. Had Ethicon acted safely and reasonably with regard to its design, manufacture and sale of its pelvic floor mesh products, serious harm and injury to patients could have been avoided.

Another Ethicon Medical Affairs Director, Piet Hinoul, testified that Ethicon knew of all of the complications BEFORE Prolift was launched: 105

¹⁰² ETH.MESH.00583446 – 5/4/06 email from Gene Kammerer re French Regulatory and Particle Loss

¹⁰³ ETH.MESH.0058448: Email re Urethral Sling particle loss standards and AFNOR

¹⁰⁴ David Robinson Testimony 199:9-200:2

¹⁰⁵ Hinoul trial testimony *Gross, et a. vs Gynecare, et al* 01/16/13:1151:5-1156:14; 1087:1-17; 1058:22-1059:3

- Mesh exposure that is difficult to treat and requires multiple operations;
- Serious complications with a significant effect on the quality of life for the patient;
- Narrowing of the vaginal wall;
- Significantly scarred vagina;
- Life-long risk of erosions;
- Retractions that could lead to recurrence of prolapse, postoperative pain and dyspareunia;
- Prolonged or Permanent inability to void their bladder;
- Every reoperation is considered an adverse event;
- Vaginal rigidity in the context of mesh retraction;
- Potential cause of recurrence cause by individual anatomical variation;
- Complex mesh erosion;
- Chronic pelvic pain syndrome;
- Life-changing symptoms despite multiple interventions to treat Prolift complications;
- Possible inability to achieve complete symptom resolution;
- Mesh contraction can be difficult or impossible to treat;
- Mesh contraction can cause severe pain that may never resolve despite conservative and surgical treatment;
- In the event of mesh related complications, it may be difficult to safely and effectively remove the mesh;
- Some patients will have a severe inflammatory reaction to the mesh, which will be chronic;
- The inflammatory reaction to the mesh will, in some women, result in the formation of scar plating/bridging fibrosis across the mesh. This increased the risk of complications;
- Some patients will suffer complications that will make it impossible for them to have comfortable sexual relations for the rest of their lives;

In his Clinical Expert Report supplement of August, 2012, Dr. Hinoul listed the multiple "harms and hazards" of Prolift +M that he said were known before both Prolift and Prolift +M went on the market to be permanently implanted in women. ¹⁰⁵

The medical literature is replete with peer-reviewed reports documenting complications with surgical mesh for pelvic organ prolapse and stress urinary incontinence. 106,107,108,109,110,111,112,113,114

¹⁰⁵ ETH.MESH.08315779 – September 24, 2012 Prolift +M Clinical Expert Report by Piet Hinoul

¹⁰⁶ Klosterhalfen, B., K. Junge, and U. Klinge, The lightweight and large porous mesh concept for hernia repair. Expert Rev Med Devices, 2005. 2(1): p. 103-17.

¹⁰⁷ Elmer C., Altman D., Ellstom Engh M., Axelsen S., Vayryen T., and Falconer C.; Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse. ACOG Vol. 113, No. 1, January 2009

¹⁰⁸ Elmer C, Blomgren B, Falconer C, Zhang A, and Altman D; Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery. The Journal of Urology Vol. 181, 1189-1195, March 2009

In addition, there have been 'Ethicon Expert Meetings' during which the issue of complications, including infection and shrinkage, were discussed. ^{115,116} I reviewed an Ethicon document entitled "WW Customer Complaints" from March 16, 2005 to July 10, 2008. ¹¹⁷ In the WW Customer Complaints document a total of 231 complaints were recorded as being received on Prolift, 145 of these reported as "Serious Injury". The top complaints were: mesh exposure (14%); erosion (12%); pain (12%); bladder perforation (9%); dyspareunia (5%); bleeding (5%); recurrence (5%). Because Ethicon acknowledged that "It is obvious that in most cases the terms 'exposure', 'erosion', and 'extrusion' are used interchangeably", the mesh erosion rate could be as high as 26% from this reporting. ¹¹⁸

Ethicon used Prof. Klosterhalfen as an outside pathology consultant to do histological evaluations at the Duren Institute of Technology of explanted mesh samples received by Ethicon. As of April 2008, he had analyzed 100 such samples. At that time, he prepared an "Interim Report Mesh Explants Pelvic Floor Repair". His findings, summarized, were that "Foreign body tissue reaction followed by secondary fibrosis seems to play a special role in pelvic floor repair. This is important, because soft tissue coverage is thin in pelvic floor repair. Fibrosis and folding in this are inducing mesh erosions and ulcerations".

In June 2009, Prof. Klosterhalfen prepared another interim report regarding his histological examination of another 172 prolapse mesh explants concluding: "In summary, therefore, FBRs and secondary fibrosis seem to play a significant role in prolapse repair...Fibrosis inevitably leads to mechanical irritation, particularly when wrinkling occurs, and should be seen as the basic cause of mesh-induced erosion and ulceration...infection is commonly observed following erosion in the vaginal mucosa." ¹²⁰

¹⁰⁹ Jeffrey S, de Jong P: Mesh, Grafts and Kits in Pelvic Organ Prolapse Surgery: Where are we now? aSAUGR Vol. 6, No. 1 (2008)

¹¹⁰ Blandon R, Gebhart J, Trabuco E, Klingele J, Complications from vaginally placed mesh in pelvic reconstructive surgery. Int Urogynecol J (2009) 20:523-531

Kirschner-Hermanns R, Klinge U, Klosterhalfen B, Brehmer B, Heidenreich A; What can we learn from explanted slings and meshes in pelvic floor surgery? The Journal of Urology, 1772 Vol. 183, No. 4, Supplement (2010)

¹¹² G. Welty, U Klinge, M Stumpf, B Klosterhalfen, V Schumpelick (2000) Development of new mesh materials for hernia repair and clinical outcome of different polypropylene meshes. 35th Congress of the European Society for Surgical Research 1.-3.6.2000, Malmö, in European Surgical Research 32,S1,00: S. 3

Altman D., Väyrynen T., Ellström Engh M., Axelsen S., Falconer C., (Transvaginal Mesh Group*) Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse. N Engl J Med 2011;364:1826-36.

Withagen MI, Vierhout ME, Milani AL; Does trocar-guided tension-free vaginal mesh (Prolift) repair provoke prolapse of the unaffected compartments? Int Urogynecol J. 2010 Mar;21(3):271-8. Epub 2009 Nov 10.

¹¹⁵ Klinge U, Junge K, Stumpf M (2003) Causes of recurrence after Lichtenstein tension-free hernioplasty (letter). Hernia 7: 100-101

¹¹⁶ 97. Krones CJ, Bohm G, Ruhl KM, Stumpf M, Klinge U, Schumpelick V (2003) Inguinal hernia on the Internet: A critical comparison of Germany and the U.K. Hernia. 2004,8: 47-52

¹¹⁷ ETH.MESH.01819528: WW Customer Complaints – received from Carey Brennan ¹¹⁸ ID

¹¹⁹ ETH.MESH.00006636: Klosterhalfen B., Interim Report Mesh Explants Pelvic Floor Repair

¹²⁰ ETH.MESH.02157879-02157880: Klosterhalfen B., Intermediate Report – Prolapse Mesh Explants 6/2009

Mesh erosions were becoming such a problem with Prolift that Dr. Peter Meier, a Principal Scientist with Johnson & Johnson Medical in Germany, prepared a 122-page "Clinical Evaluation Report – Mesh Erosions" in September 2010. 121 Dr. Meier reported that, "Mesh related complications may be associated with the mesh material used for reinforcement or the surgical procedure itself. Mesh material related adverse events include infections, erosions, extrusions, mesh shrinkage, vaginal granulation tissue... Additionally, functional problems such as de novo urgency, urge incontinence, dyspareunia and nonspecific pelvic pain may also be observed in certain patient groups." The number one factor that Dr. Meier lists as causing mesh erosions is "pore size and porosity of the mesh" as discussed previously above. Unfortunately, Dr. Meier incorrectly states in this report "...that pore size larger than 75 microns will reduce the incidence of mesh erosions.

As mentioned earlier, on May 18, 2011, Johnson & Johnson received the final PA Consulting Group report investigating mesh erosion. One of the things Johnson & Johnson asked these outside consultants to analyze was Dr. Meier's report from September 2010. In a 50-page report PA Consulting reported that "Of the many variables that influence mesh erosion, pore size is listed first...transvaginal implantation has a higher risk of mesh erosion than transabdominal surgery...vaginal area carries many bacteria, so it is virtually impossible to insert mesh devices without contamination...If host cells cannot clear the bacteria on the mesh surface, the mesh is irreversibly contaminated and the bacteria may remain dormant for long periods with the possibility of establishing a tissue infection later..."

In addition, on December 21, 2011 Chris Vailhe prepared a paper for Ethicon entitled "Polypropylene Mesh for Pelvic Floor Repair (PFR) – Focus on Mesh Exposure – Road to Improvement". Vailhe chose to focus the majority of the paper on "mesh exposure" as it was the highest percentage of adverse events.

I have found in my own work, by examining explanted meshes, that pore size and geometry is the most important factor in the outcome of a tissue repair with a synthetic material. By examining explanted pelvic floor repair meshes my colleagues and I found that erosions, chronic pain and nerve damage were most commonly associated with small pore meshes. ¹⁰⁹

The same holds true in hernia repair. In examining 1,000 explanted hernia meshes, infection and pain as the reason for mesh removal was most often seen in small pore meshes.⁵²

VII. ALTERNATIVE DESIGN - "PROJECT THUNDER" & "PROJECT LIGHTNING"

In 2001, Dr. Bridgette Hellhammer authored an internal document titled "Meshes in Pelvic Floor Repair – Findings from literature review and interviews with surgeons". Her conclusions were that a pelvic floor repair using a mesh implant was plausible, and "A thinner mesh than the

¹²¹ ETH.MESH.00869977-00870098 Peter Meier "Clinical Evaluation Report – Mesh Erosions"

¹²² ETH.MESH.02589032-02589079 PA Consulting report "Investigating Mesh Erosion in Pelvic Floor Repair"

¹²³ ETH.MESH.04038032-ETH.MESH.04038055 Chris Vailhe report "Polypropylene Mesh for Pelvic Floor Repair (PFR) – Focus on Mesh Exposure – Road to Improvement

i²⁴. ETH.MESH.02017169: Hellhammer, B., Meshes in Pelvic Floor Repair – Findings from literature review and interviews with surgeons. (2001)

current Prolene mesh and with some elasticity would be well accepted. Vypro would meet these requirements. A totally nonabsorbable mesh with similar mechanical properties as Vypro would also be well accepted."

In 2002 Ethicon obtained a German patent No. DE 10043396C1 20.06.2002 for a PVDF surgical implant. However, as it is now known, Gynemesh PS was chosen for Prolift, apparently for no other reason that it "pre-ordained". The physicians who developed the TVM technique (Cosson and Jacquetin), were aware of the complications associated with Prolift mesh and implored Ethicon to consider a different mesh material in 2004, before Prolift was launched for sale. In fact, Dr. Cosson advised Ethicon employee, Scott Ciarrocca in 2003 that the problems related to mesh are "more erosion, retraction". In another email dated May 10, 2004, Ethicon employee Ophelie Berthier tells her co-workers that the inventors of the TVM technique, Pr. Jacquetin and Dr. Cosson are concerned about the shrinkage of mesh and its direct relationship to pain and dyspareunia. It was well understood and recognized that the complications associated with Prolift mesh were occurring frequently enough to validate the need for a new material.

In February, 2004, during a meeting with Murty Vykarnam and Mora Melican, it was determined that erosion is still the primary concern of mesh products as it is the cause of scarring around the implant. It was also noted at that same meeting that contraction of the scar tissue has been reported and that contraction is linked to severe clinical complications. The development of Prolift +M, a device utilizing a new material and new design for pelvic floor repair, eventually became known as "**Project Lightning**" and began in early 2006.

Gene Kammerer, one of Ethicon's top R&D engineers advised his colleagues that the issue they need solve is that of scar contracture of the mesh, which leads to: recurrence, pain, stiffness, erosion and dyspareunia. This information was known in April 2005, a month after Ethicon began to market and sell Prolift. Already in 2005, they were discussing whether Ultrapro was the better choice of material of the Gynemesh PS used in Prolift.

In a February 2007 PowerPoint presentation titled "Project Lightning Update", Ophelie Berthier, Marketing Manager EMEA described the new mesh material, Ultrapro, as a partially absorbable, monofilament, large pore, pliable, vaginally compliant mesh with little memory. Ms. Berthier states that, in general surgery (hernia), Ultrapro had proven to cause less inflammation, induce less fibrosis, have better integration to host tissues, maintain the mobility of the abdominal wall, have an outstanding biocompatibility, and improve patients' quality of life. During the first cadaver lab of Project Lightning, Dr. Lobodasch found a significantly smaller amount of "curling" in the mesh arms after implantation; after the second cadaver lab, Ethicon's

¹²⁵ German Patent No. DE10043396C1 20.06.2002

¹²⁶ ETH.MESH.02270823: Email dtd 2/26/04 from Joshua Samon to Scott Ciarrocca, et al. Re: mesh implants – user needs

¹²⁷ ETH.MESH.02270724: Email dated July 19, 2003 from Cosson to Ciarrocca re mesh problems

¹²⁸ ETH.MESH.00584846: May, 2004 email string from Ophelie Berthier forwarding the concerns of Cosson and Jacquetin

¹²⁹ ETH.MESH.01220730 – Questions and Concerns raised at February 10, 2004 meeting

¹³⁰ ETH.MESH.00742724: PPT by Ophelie Berthier "Ethicon Women's Health & Urology: Project Lightning Update"

Key of Opinion Leader, Dr. Vince Lucente stated, "Keep this one and throw the rest out...This feels like a piece of vaginal wall..." 131

Ethicon also had a renewed interest in trying to develop Pronova (PVDF) sutures as a pelvic floor mesh. As a result, they began a new project to investigate this PVDF PFR design concept through a new project dubbed by Ethicon as "**Project Thunder**". August 14, 2007 Project Thunder meeting minutes reported that Ultra-light PP mesh was ready, Pronova in process. Pros and cons of Pronova to PP: Pro: Softness, Elasticity, better biocompatibility, less "aging" long time breakage, easier to manufacture and sterilize. Con: "May be more expansive (sic)". Preclinical on collagen coated PP started – histology results expected late September. ¹³²

Prolift +M using Ultrapro mesh was launched and received 510(k) clearance in May 2008, four years after the developers of the TVM technique suggested a different mesh material for use in the Prolift kit and 10 years after Ethicon had learned through the research of myself and my colleagues of safer alternative mesh designs. Also, despite the stated design and complication advantages of Prolift +M over Prolift, Ethicon continues to market and sell what they have essentially claimed as an inferior device.

As per a Power Point presentation, during the period from November 2010 to October 2011 **Project Thunder** was "killed" due to "tech push". Although it is unclear as to what "tech push" infers, in multiple places, Ethicon seems to focus on the fact that PVDF costs more than PP. In their May 9, 2008 Thunder MGPP presentation, one slide is particularly telling. It shows the PVDF products all out-performing Gynemesh PS and Ultrapro in every design attribute except one...cost. Project Thunder was "killed" by Ethicon despite the fact that at multiple meetings, it was described as the "holy grail" of pelvic floor meshes, whereas Project Lightning (Prolift +M) was characterized as the "quick hit".

The Ethicon Mesh Technology Center was also working on a "Exposure Reduction Mesh" specifically to address their need to reduce the occurrence of erosion in their products. In a 2010 PowerPoint presentation, it is noted that they need to "advance material science in PF repair by reducing mesh exposure (occurrence ~ 10%). This again shows their knowledge of erosions and the importance and reducing them. In 2011, during their EWHU Pelvic Floor Pipeline Update, it was again noted that they need to create a mesh to reduce the 10% occurrence of mesh. In this presentation, they state that phase I as "What is Mesh Exposure". This presentation comes six years after Prolift was marketed, Ethicon was still attempting to define what the term "exposure" meant and how that plays a part in the clinical implications of the mesh.

¹³¹ ETH.MESH.00832555: Thunder Meeting Minutes dtd 4/12/07

¹³² ETH.MESH.00869908: Thunder Meeting Minutes dated 8/14/07

¹³³ ETH.MESH.00562421: untitled PowerPoint update from November 2010 – October 2011

¹³⁴ ETH.MESH.02227224: PowerPoint Presentation dated 05/09/08 titled MGPP Thunder Decision Meeting

¹³⁵ ETH.MESH.00869908: Thunder Meeting Minutes dated 8/14/07

¹³⁶ ETH.MESH.02227224: PowerPoint Presentation dated 05/09/08 titled MGPP Thunder Decision Meeting

¹³⁷ ETH.MESH.01819833: GAT PPT

¹³⁸ ETH.MESH.071490420: WW ETHICON Mesh Technology Center Powerpoint Presentation

Ethicon was aware of the fact that 48% of complication were related to mesh. They were aware that the high erosion rates and mesh shrinkage relate to severe complications include pain, dyspareunia, recurrence and the necessity of additional surgeries. ¹³⁹

VIII. SUMMARY OF OPINIONS

Prior to launching Prolift for sale in the U.S., according to their own documents, Ethicon was aware of the most important design requirements for a safe pelvic floor mesh product.

According to their documents, Ethicon also knew why these design requirements were so important in terms of patient safety.

However, as is also stated in their documents, Ethicon was aware of the challenges and uncertainties of designing a safe mesh for the pelvic floor; that the design of Prolift did not meet all their claimed optimal design requirements; and that as a result, this led to patient complaints and complications.

Ethicon has a long history of manufacturing surgical meshes that are intended to be permanently implanted by doctors in patients' bodies. They likewise have a long history of reported complications with their prosthetic meshes. With their experience from complications associated with some of the poor design characteristics in hernia meshes, Ethicon knew that poor design leads to poor outcome.

Through my team's collaborative efforts with Ethicon in the late 1990's and early 2000's, Ethicon learned that the development of an optimal surgical mesh design for any application has to consider first, the polymer; second, the biomechanics (physiological requirements) as to strength, elasticity and structural stability; and third, the structure of the device in terms of geometric design, knitting characteristics, fiber size and pore size. Ethicon knew that the result of these design considerations and choices would influence the tissue reaction, primarily the intensity of the inflammatory and fibrotic response, thereby directly affecting the biocompatibility of the device and thus the clinical outcome.

However, despite this knowledge, Ethicon failed to appropriately design and test its pelvic mesh kit, Prolift, to determine if these unintended and adverse events would occur when implanting Gynemesh PS permanently into a woman's pelvic tissues resulting in significant morbidity to women around the world. Regardless of whether or not Prolift is successful, on the one hand, by holding the pelvic organs in place, it is a disastrous failure if it leads to long-term serious complications like erosions, chronic pain, permanent sexual dysfunction, chronic wound healing issues and chronic infections, all of which have been seen and reported within the literature and in Ethicon's internal documents and its employees deposition testimony.

Ethicon has stated repeatedly in its documents that it had a very poor understanding of the biomechanics of the pelvic floor, which apparently continues to this day. As such, it is impossible to establish reliable parameters for the design of the device. Furthermore, despite Ethicon's apparent knowledge of the significant amount of mesh shrinkage experienced by

¹³⁹ ETH.MESH.00579556: 2010 Mesh Platform Review

patients in whom Prolift had been implanted, the potential causes of mesh shrinkage, as well the resultant patient complications that could occur as a result of this shrinkage, they did no testing nor made any design changes to Prolift in order to reduce the occurrence of this known and serious complication. Failure by Ethicon to properly study and/or make the necessary design changes to avoid this and the other safety hazards mentioned in this report was improper, irresponsible and threatened patient safety.

I reserve the right to modify these opinions as necessary based upon any new or additional information or data that I may obtain or with which I am presented.

IX. EXHIBITS

All exhibits that will be used to support my finding and opinions are included above and listen below in Appendix "B"

X. RECENT TESTIMONY

I have testified as an expert at the following trial:

Linda Gross, et al. vs. Gynecare, et al.; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08

Carolyn Lewis (2:12-cv-04301)

XI. COMPENSATION

I am compensated for investigation, study and consultation in the case at the rate of \$500.00 per hour.

This 30th day of June, 2014

Prof. Dr. med. Uwe Klinge

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EXHIBIT

A

CV Professor Dr. med. Uwe Klinge

Born at 30.4.1959 in Wilhelmshaven, Germany

1964-1977 Wilhelmshaven Primary, secondary, high school

1977-1983 RWTH Aachen Medical school

Medical profession

12/1983 - 2/85: military service VKK 321, Düsseldorf

1.3.1985: surgical resident ship at the Surgical Department of the University Hospital at

the RWTH Aachen (Head Prof. Reifferscheidt, after 12/85 Prof.

Schumpelick, after 3/2010 Prof. Neumann)

1992: Thesis at the Department for biochemistry, Prof. Gersonde at 29.4.1985 "In-

vitro investigation of the oxygen binding curve of human erythrocytes in the

presence of glucose and insulin "

15.12.1993: Specialist for general surgery

since 15.10.1999: Oberarzt of the surgical Department

1/2000 Venia legendi for Surgery, Habilitation with the title "Use of alloplastic

meshes for the repair of abdominal wall hernia: optimisation by adjustment to

the physiological requirements "

Since 15.10.2000: Principal investigator of the surgical department

21.3.2002: specialist for surgical intensive care medicine

1.1.2003 - 1.11.2006: Assistant medical director

21.7.2004: Specialist for visceral surgery 13.12.2005: appointment as a.pl. Profess

1.11.2006-28.2.2009: Cooperation with the Institute for applied medical engineering of the

Helmholtz institute

1. Scientific work

- Pathophysiology and treatment of abdominal wall hernia
- Biomaterials and tissue response
- Impact of altered ECM for wound healing and cancer development
- Analysis of biological networks
- Identification of prognostic markers
- Optimisation of staplers

Member of the Editorial Board of World Journal of Gastrointestinal Surgery (WJGS)

Member of the scientific committee for the research program START of the university clinic

Member of the German Society of surgeons

Member of the European Hernia Society

Member of the German Hernia Society

Publications

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- 169. U. Klinge: The CRPS as concept for chronic pain? Belgium surgical society 2007, 29.11.2007, Brüssel
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- 172. U. Klinge Polyester, PVDF oder PTFE kein, zwei oder vier Fluoratome? 2. Berliner Hernientage 25.-26.1.2008 Berlin

- 173. U. Klinge Schluß mit der Suche nach dem Gold-Standard! 2. Berliner Hernientage 25.-26.1.2008 Berlin
- 174. U. Klinge: Experimentelle Untersuchungen zu alloplastischen Materialien: Welche Eigenschaften sollten sie für die Verwendung am Beckenboden haben? 17. Urolog. Winterworkshop Leogang 28.01. 01.02.2008
- 175. U. Klinge: Die Chirurgie der Leistenhernie von der Stange oder nach Maß? Fortbildungsveranstaltung der AEKNO, Kreisstelle Duisburg 20.2.2008
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- 177. U. Klinge: Welche Hernie braucht ein Mesh? 1. Tagung der Schweitzer Herniengesellschaft in Bern, 4.4.2008
- 178. U. Klinge: Welche Probleme können bei der Verwendung von Netzen in der Hernienchirurgie auftreten? 125. Kongress der DGfC, 22.-25.4.2008, Berlin
- 179. U. Klinge: Low-weight polypropylene mesh: what is the clinical importance of the porosity for hernia repair? 30. congreß of the EHS, Sevilla, Spain: 7-10.5.2008
- 180. U. Klinge: Grundlagen der Hernienreparation aus Sicht des wissenschaftlichen Chirurgen. 5. Tagung der Deutschen Hernien-Gesellschaft, Baden-Baden:29.-31.5.2008
- 181. U. Klinge: Postoperative CRPS in inguinal hernia patients. 5. Suvretta-Workshop, St. Moritz: 1.-7.7.2008
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- 186. U. Klinge: What should be considered for selection of mesh material. AHS, Beijing, 1.-2.11.2008
- 187. U. Klinge: The CRPS after groin hernia repair. AHS, Beijing, 1.-2.11.2008
- 188. U. Klinge: Hernia repair tailored to the patient instead of using a gold standard?. AHS, Beijing, 1.-2.11.2008
- 189. U. Klinge: Future perspectives in textile implants. AHS, Beijing, 1.-2.11.2008
- 190. U. Klinge: Update mesh. Shanghai. 28.11.2008
- 191. U. Klinge: Hernia and Collagen. 4. Rotterdam interactive congress for hernia, 21.11.2008, Rotterdam NI.
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Oral presentation, on invitation:

- 1. U.Klinge Review of literature and experimental results of mesh surgery Expert-Meeting Suffretta-House St. Moritz Feb. 1994
- 2. U.Klinge Pathophysiologie der Narbenhernie Chirurgentag Nürnberg 24.10.1996
- Conze, J., U Klinge (1998) Biocompatibility of biomaterials clinical and mechanical aspects. II Suvretta meeting: abdominal wall: function, defects and repair. 8.-14.3.1998 St. Moritz Swiss
- U. Klinge, B Klosterhalfen (1998) Biocompatibility of biomaterials experimental aspects. II Suvretta meeting: abdominal wall: function, defects and repair. 8.-14.3.1998 St. Moritz Swiss
- B. Klosterhalfen, U. Klinge (1998) Biocompatibility of biomaterials histological aspects. II Suvretta meeting: abdominal wall: function, defects and repair. 8.-14.3.1998 St. Moritz Swiss
- 6. U. Klinge (1998) Meshes zur Hernienreparation. 7. Interdisziplinäres Forum der Förderation operativer medizinisch-wissenschaftlicher Fachgesellschaften 17.10.1998 Wiesbaden
- 7. U. Klinge (1999) Chirurgie der Narbenhernie. 5. Kölner Tagung ambulantes Operieren. Köln, 7.5.1999
- 8. U. Klinge (1999) Pathophysiologie der Bauchdecke. Weißenseer Operationskurs 24.9.99
- U. Klinge (1999) Rezidive und Patientenkomfort im Langzeitverlauf. Weißenseer Operationskurs 24.9.99
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- 12. U. Klinge (3.5.2000) Biomaterialien in der Hernienchirurgie. FomwF, 117. Kongreß der Deutschen Gesellschaft für Chirurgie 2.-6.5.2000, Berlin
- 13. U. Klinge (4.5.2000) Epidemiologie und Pathophysiologie der Bauchwanddefekte. Narbenhernie, 117. Kongreß der Deutschen Gesellschaft für Chirurgie 2.-6.5.2000, Berlin
- 14. U. Klinge (26.5.2000) Anatomy and physiology of the abdominal wall. Laparoscopic incisional hernia repair a standard therapy? Rastatt, 25.5-27.5.2000
- 15. U. Klinge (2.6.2000) Technical aspects, abdominal wall physiology, integration and inflammatory reaction. 35. ESSR-Kongreß, Malmö, 1.-3.6.2000
- 16. U. Klinge (2.6.2000) News and future outlooks. 35. ESSR-Kongreß, Malmö, 1.-3.6.2000
- 17. U. Klinge (2000) Pathophysiologie der Bauchdecke. Weißenseer Operationskurs 2000, 8.9.2000, Berlin
- 18. U. Klinge (2000) Rezidive und Patientenkomfort im Langzeitverlauf. Weißenseer Operationskurs 2000, 8.9.2000, Berlin
- 19. U. Klinge (2000) Netzimplantate in der Hernienchirurgie Charakteristika und Anforderungen.Netzimplantate 22.-23.9.2000, Würzburg
- 20. U. Klinge (2000) Minimierte Polypropylen-Netze zur präperitonealen Netzplastik prospektive Studie. 22.-23.9.2000, Würzburg
- 21. U. Klinge (2000) Implantierbare Netze in der Chirurgie Nutzen oder Risiko? Fortbildungsveranstaltung der Kreisstelle Mülheim/Ruhr 10.10.2000, Evang. Krankenhaus Mülheim a. d. Ruhr
- 22. U. Klinge, B. Klosterhalfen, V. Schumpelick (2000) Kollagenstoffwechselstörungen und Konsequenzen für die chirurgische Therapie. Gründungskongress der Arbeitsgemeinschaft Wundheilung der DGfC, 13-14.10.2000 Tübingen
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- 27. Klinge U (2001) Welcher Patient bekommt ein Rezidiv? Aktueller Stand der Forschung. Workshop Viszeralchirurgie 24.-26.10.2001
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- 104. U. Klinge: Die "männliche Schlinge" zur Therapie der Harninkontinenz. AGKAMED "Neue Behandlungswege der männlichen Inkontinenz", Berlin, 12.5.2009
- 105. U. Klinge: Was bedeutet Biokompatibilität in der Chirurgie. 1.5.2009 München, Jahreskongreß der DGFC
- 106. U Klinge: Lightweight mesh Konzept. 28.4.2009 München, Jahreskongreß der DGFC
- 107. U Klinge: Welche Netze für die offene/laparoskopische Narbenhernienreparation?. 30.4.2009 München, Jahreskongreß der DGFC
- 108. U. Klinge: Biomechanische Anforderungen: Was sollen und können Netze leisten? 30.1.2009, Berlin 3-Chirurgen
- 109. U. Klinge: What has to be considered for selection of alloplastic nets and slings at the pelvic floor? 28.3.2009, Dijon
- 110. U. Klinge: Leuven Aachen Rotterdam Herniosis Studygroup LARHS 10.4.2009, Leuven
- 111. U. Klinge. Biologicals für die Hernienchirurgie? Jahreskongreß der Deutschen Herniengesellschaft in Neuss, 19-20.6.2009
- 112. U. Klinge. Mesh structure or confusion? 4. Interrnationaler Welthernienkongreß in Berlin 9.-12.9.2009
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- 115. U.Klinge: Update Narbenhernienchirurgie unter Einbeziehung von Grundlagen der Netzstabilität. Chirurgische Abteilung, Uniklinik Essen, 26.10.2009
- 116. U. Klinge: Principles of hernia repair. Masterclass Baden-Baden, 20.11.2009
- 117. U. Klinge: Biologicals. Masterclass Baden-Baden, 21.11.2009
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- 124. U. Klinge: the ideal mesh. Oslo 4/2010
- 125. U. Klinge: What is the ideal mesh? Dubai 4/2010
- 126. U. Klinge: biologicals for every henria? Dubai 2010
- 127. U. Klinge: mesh classification? Dubai 2010
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- 130. U.Klinge: Wie kann man Meshes klassifizieren? BvMed 2.7.2010
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- 133. U. Klinge: Basic principles of mesh implants and actual status of knowledge. Liedl, München Bogenhausen, 13-14.10.2010
- 134. U. Klinge: Alloplastische Materialien in der Hernienchirurgie was gibt es Neues? Wilhelmsburger Hernientage 23-24.10.2010
- 135. U. Klinge: Biomechanics, immunology and tissue response to the mesh. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro

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- 137. U. Klinge: Sublay, Why and How? Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
- 138. U. Klinge: Paracolostomic hernia. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
- 139. U. Klinge: PVDF. Brazilian hernia Congress November 25th to 27th, 2010 InterContinental Hotel Rio de Janeiro
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- 141. U. Klinge: Grundlagen und Materialien. Berliner Hernientage 24-29.1.2011
- 142. U. Klinge: Classification of surgical meshes for hernia repair. EHS, Gent, 11-13.5.2011
- 143. U. Klinge: Risk factors for incisional hernia development. EHS, Gent, 11-13.5.2011
- 144. U. Klinge: Statistics and analysis for biological material in hernia treatments the current status quo. Cook Symposium. Berlin, 19-20.5.2011
- 145. U. Klinge: Biologische Netze heute. 1. Düsseldorfer Herniensymposium. 2.4.2011
- 146. U. Klinge: Chaos bei den Kunststoffnetzen: Vorschlag zur standardisierten Einteilung. DHG Oldenburg, 26-28.5.2011
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- 148. U. Klinge: Surface modification: do we really need it? EHS Winter conference, Madonna di Castillo, 10-12.3.2011
- 149. U. Klinge: Abdominal wall hernia, current update. 10. 12.11.2012 Masterclass Baden-Baden
- 150. U. Klinge: Prophylaxe der Hernienentstehung. Symposium Rotkreuzklinikum München. 25.11.2012
- 151. U. Klinge: "Surface modification to direct tissue response" RICH, Rotterdam, 13.1.2012
- 152. U. Klinge: Grundlagen und Materialien. Hernia Kompakt, Hamburg, 19.1.2012
- 153. U. Klinge: Klassifikation von Netzimplantaten in der Hernienchirurgie. 4. Wilhelmsburger Hamburg, 20.1.2012
- 154. U. Klinge: Evidence based medicine Was sollen wir glauben? 25.4.2012, DGfC, Berlin
- 155. U. Klinge: Uni Essen Chirurgie-Fortbildung: Hernienchrirugie wann welches Netz. 21.5.2012
- 156. U. Klinge: Classification of meshes for risk assessment. EuraHS, Brüssel, 7.6.2012
- 157. U. Klinge: Change in pore size and weight of abdominal wall meshes: What did it bring us so far? Brüssel, 25.10.2012
- 158. U. Klinge: Materialien in der Hernienchirurgie. Hernia Kompact München, 24-26.10.2012
- 159. U. Klinge: EBM was sollen wir glauben. Hernie interaktiv, München, 27.10.2012
- 160. U. Klinge: From view of experimental surgeon meshes for pelvic floor. Munic, 17.11.2012
- 161. U. Klinge: Biomechanic aspects of meshes for pelvic floor surgery. Expert class Cologne Prof. Jäger, 7.-8.12.2012
- 162. U. Klinge Klassifikation der Netze. 25.-26..1.2013, 6. Berliner Hernientage
- 163. U. Klinge Sichtbare Netze, erste Ergebnisse, 25.-26.1.2013, 6. Berliner Hernientage.
- 164. U. Klinge Netz- und Materialentwicklung: Biomaterialien in der Chirurgie: Fluch oder Segen ? 59. Kongress der Nordrhein-Westfälischen Gesellschaft für Urologie. 11. 12. April 2013 |Rheinterrasse Düsseldorf.
- 165. U. Klinge: Individual patient centred outcome research as alternative to randomized controlled trials (RCT). Gdansk EHS 14.5.2013, EHS

- 166. U. Klinge: Ist Randomisierung der Schlüssel zur evidenzbasierten Hernienchirurgie? Cottbus 7.-8.6.2013, DHG
- 167. U. Klinge Das richtige Netz TAPP / TEP / offen. Saale-Unstrut, 29.6.2013
- 168. U. Klinge. Textile meshes in Surgery:
 - FDA Warnings New Standards Registries What can we learn from Hernia Surgery? Barcelona ICS. 29.8.2013
- 169. U. Klinge Moderne Netz-Technologie. 2. Düsseldorfer Hernien-Symposium Zarras, 26.9.2013

Grants

				period	
	Principal investigator, co-workers	topic	Supporter, duration		Amount of resources
	Klinge, Höer	Panacryl-Fadenstudie	Ethicon /	1999-2002	260.000
	<u> </u>	•	3 Jahre		
	Klinge, Welty	Internationale Vypro-Studie	Ethicon / 3 Jahre	1999-2002	54.000
	Klinge, Welty	SHM-Studie	Ethicon / 2 Jahre	1997-1999	262.000
	Klinge	Kollagen-Studie	Ethicon / ½ Jahr	1999	30.000
TV 9	Klinge	Verwendung von Biomaterialien beim Bauchdeckenverschluß	BIOMAT 4 Jahre	1995-1998	208.107
TV 41/42	Klinge/Steinau	PVDF-Mesh	BIOMAT 2 Jahre Nachfolgeproje kt 2 Jahre	1999-2000 2001-2002	347.940
	Klinge	Mesh-Entwicklung	Ethicon	2000-2003	375.000 Kostenstelle: 9876170 Anforderungsn r.: 98761770
TV 66	Mertens, Klinge	Mesh-Fibroblasten	BIOMAT	2001-2002	330.000
TV 61	Bertram, Tietze, Klinge	Kokulturen	BIOMAT	2001-2002	210.000
FEG/BMB F	Klinge, Klosterhalfen	Entwicklung von neuartigen bioverträglichen Netzmaterialien zur anatomisch angepaßten chirurgischen Hernientherapie - Beschichtete Meshes	03N4024 FEG-065/1- 2001	1.3-2001- 2004	358.824,-
DFG	Klinge, Klosterhalfen, Mertens	Kollagen und Hernie	KL 1320/2-1	21.6.2001- 21.6.2003	350.000,-
Ethicon	Schumpelick,	Optimierung von Mesh-Strukturen	370253	1.4.2003-	360.000 €

				period	
	Principal investigator, co-workers	topic	Supporter, duration		Amount of resources
	Klinge, Stumpf, Junge, Schachtrupp, Steinau, Schwab	70 .		31.3.2006	
DFG	Lynen-Jansen Mertens Klinge Jansen	Einfluß von Biomaterialien auf die MMP-2 Genexpression in vivo	JA1123/1-1	2004-2005	120.000 Euro
DFG- Projekt	Lynen-Jansen Mertens Klinge Jansen ,	Untersuchungen zur Gewebe- Integration von Biomaterialien bei selektiver Blockade der TNFα- abhängigen MMP-2 Expression'	DFG JA 1123/1-2,	Laufzeit 2 Jahre, Umfang Start 2008	ca. 120.000 Euro,
INNONET	HIA und Frauenhofer	Die sichere Naht	VDI/VDE	2/2008- 2011	Gesamtvolume n 1,1 Mill €
Mesh insight	FEG und UK- Aachen Klinge U, Otto J, Krämer N, Obolenski B:	Sichtbarmachung von textilen Implantaten im MRT durch Einlagerung von superparamagnetischen Eisenoxid- Nanopartikeln. Innovationswettbewerb 2007 des BmbF zur Förderung der Medizintechnik, 18.10.2007	BMBF 01EZ0849	1.4.2008- 31.1.2011. 3.2008- 1.2.2011	Gesamtvolume n ca. 900.000€
	Kämmer, Otto, Klinge	PVDF-Mesh Beschichtung mit NN- Hormonen	ESAC	2008	12 000€
Bioinside	FEG/Fiebeler/B erlin	Beschichtung mit DHEA	BMBF BioInside 13N9827- 13N9833 PN 372552	2008-2010	70 000€
	Klinge	InnoMeT.NRW: Patientenadaptierte Medizintechnische Lösungen für die Kardiovaskuläre Therapie	005-1003-0067 IAN 700584	1.8.2010- 31.7.2013	270 000
	Klinge	Elastisches Netz-Implantat für die Chirurgie am Zwerchfell (Hiatus-Mesh)	ZIM-Projekt KF2621701AJ0	14.4.2010- 31.10.2011	110 000€
	Klinge/Tolba	Covidien Stapler Pase I	372708	1.2.2010- 31.1.2011	120 000 Eur
	Klinge/Tolba	Covidien Stapler Pase II	372708	1.4.2011- 31.3.2012	180 000 Eur
	Klinge et al, ZIM 3D	3D Implantat	ZIM / AiF 13EZ1201C	1.10.11- 30.9.2013	174 893 €
	Klinge et al. ZIM Hiatus- Mesh	Zwerchfell-Netzimplantat	ZIM / AiF KF2621701AJ0	1.4.10- 31.11.2011	110 365 €
	Klinge et al E-	Elastisches Mesh	01EZ1201C	1.6.2012-	240 000€

Principal investigator, co-workers		Supporter, duration	period	Amount of resources
	topic			
Mesh BMBF			31.5.2015	
(DLR)				

Patents:

02754251.3-2107-DE0202287 FEG Textiltechnik vom 25.6.02: Textiles Implantat mit monofilen Polyvinylidenfluorid-Fäden

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"Einstückiges Stomaunterstützungsimplantat" WO 2008/031411 A1
"Medizinisches Implantat mit Oberflächenbeschichtung" AZ 10 2009 005 792.7
"Meshförmiges Implantat" (Mesh mit Ferrofluiden) PCT/DE 2008/000805
"Textiles Intraperitoneal-Mesh" DE 10353930.1
"Textiles Erzeugnis mit Oberflächenmodifikation und entsprechendes Verfahren zur Oberflächenmodifikation" PCT/DE02/04291
"Textiles Implantat" WO PCT/DE02/02287
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EXHIBIT

B

Date	Bates Number	Title
November 2010-		
October 2011	ETH.MESH.00562421	Untitled PPT update
		Email from David Robinson to Dr. Vincent Lucente
3/26/2008	ETH.MESH.02170708	re: UP
		David Robinson, Gynemesh PS Clinical Expert
	ETH.MESH.01760854	Report
8/14/2007	ETH.MESH.00869908	Thunder Meeting Minutes
7/31/2007	ETH.MESH.01819505	Thunder Meeting Minutes
		"Exploratory Program 'Thunder' A Material designed
		for Pelvic Floor" Powerpoint presentation By:
	ETH.MESH.01405166	Clifford Volpe and Peter Meier
4/12/2007	ETH.MESH.00832555	Thunder Meeting Minutes
		"Ethicon Women's Heath & Urology: Project
	ETH.MESH.00742724	Lightning Update"
		Email from Gene Kammerer to Quentin Manley et al
2/13/2006	ETH.MESH.00585937	re: TVM Discussions
		Email from Joshua Samon to Scott Ciarroca et al. re:
2/26/2004	ETH.MESH.02270823	mesh implants - user needs
		Email from Kelly Brown to Gene Kammerer re:
1/18/2005	ETH-18761	Proposal for work with CBAT
		Email from Vincenza Zaddem to Scott Ciarrocca re:
3/25/2004	ETH.MESH.01988643	disclosure questions
		Holste, J; Test report No.: B0086/02,
	ETH.MESH.01424246	Histopathological report/Immunohistochemical report
		Hellhammer, B., Meshes in Pelvic Floor Repair –
		Findings from literature review and interviews with
2001	ETH.MESH.02017169	surgeons.
		Chris Vailhe report "Polypropylene Mesh for Pelvic
		Floor Repair (PFR) – Focus on Mesh Exposure –
	ETH.MESH.03719177	Road to Improvement
		Klosterhalfen B., Interim Report Mesh Explants
06/2009	ETH.MESH.02157879	Pelvic Floor Repair
		WW Customer Complaints – received from Carey
	ETH.MESH.01819528	Brennan
		Email from Sean O'Bryan to Scott Ciarrocca re: IFU
1/13/2005	ETH.MESH.02286052	Prolift
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		Reconstructive Surgery. The Journal of Urology Vol.
03/2009	ETH.MESH.00017369	181, 1189-1195, March 2009

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01/2009	ETH.MESH.00017239	Prolapse. ACOG Vol. 113, No. 1, January 2009
		Memo to Sunny Rha re: Global Regulatory Strategy -
2/1/2006	ETH.MESH.0394544	Gynecare TVT - Laser Cutting Project
		Email From Dan Lamont to Jacqueline Flatow re:
		!!!!!GREAT NEWS FOR TVT LASER CUT
11/21/2005	ETH.MESH.00301741	MESH!!!!!
		Letter from Carol Holloway to Herve Fournier re:
10/12/2005	ETH.MESH.0353750	TVT Device, Blue Mesh
	ETH.MESH.02059212	Prolift Surgical Guide
		Pariente J-L; An independent biomechanical
		evaluation of commercially available suburethral
	ETH.MESH.01221055	slings. Issues in Women's Health
6/6/2000	ETH.MESH.03904451	Meshes in Pelvic Floor Repair
11/22/2006	ETH.MESH.02992137	Lightning Clinical Strategy
		"State of the knowledge in 'mesh shrinkage' - What
4/5/2007	ETH.MESH.01218361	do know" by Kerstin Spychaj
3/4/2008	ETH.MESH.00832562	Thunder Meeting Minutes
12/18/2007	ETH.MESH.00832562	Thunder Meeting Minutes
		Velemir L, Amblard J, Fatton B, Savary D, Jacquetin
		B, Transvaginal mesh repair of anterior and
		posterior vaginal wall prolapse: a clinical and
		ultrasonographic study. Ultrasound Obstet Gynecol
2010	ETH.MESH.01192895	(2010)
		PA Consulting report "Investigating Mesh Erosion in
6/22/2011	ETH.MESH.07192929	Pelvic Floor Repair"
		Email from Dan Smith to Matter Henderson, et al. re:
2/27/2008	ETH.MESH.03731339	tape position at rest
2/28/2005	ETH-03558	DDSA
		Email from Vincenza Zaddem to Vernon Ghee et al.
		re: Mesh pore size - tissue compliance and
2/17/2011	ETH.MESH.01264497	contraction
		Email from Dr. Piet Hinoul to Dr. David Robinson,
1/17/2010	ETH.MESH.01785259	et al. Re: +M relaxation
		Email from Dr. Joerg Holste to Jonathan Meet, et al.
4/22/2009	ETH.MESH.02148431	re: Question on Monocryl absorption
11/18/2008	ETH.MESH.00008072	Ethicon PFR online training course
		Email from Vincenza Zaddem to David Robinson re:
8/23/2007	ETH.MESH.00000272	macroporous - lower limit of pore size
3/28/2007	ETH.MESH.00593165	Vailhe Technical report
		"R&D Perspective - The Journey from Prolift to
	ETH.MESH.00237968	Prolift +M" Powerpoint by Cliff Volpe

		"Factors Related to Mesh Shrinkage" by Kerstin
2007	ETH.MESH.01782867	Spychaj
2/23/2007	ETH.MESH.02017152	Expert Meeting Minutes
6/2/2006	ETH.MESH.00870466	Expert Meeting Minutes
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6/14/2006	ETH-83454	al. re: Mesh Microns
		David Robinson, Gynecare Prolift +M Pelvic Floor
2/5/2008	ETH.MESH.01259495	Repair System Clinical Expert Report
		Ethicon Corporate Product Characterization anayslis
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	ETH-00291	GPS for Pelvic Floor Repair
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2005	ETH.MESH.02232937	hernia repair .
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2004	ETH.MESH.00280338	Technique;
		Email from Gene Kammerer to Georgina NG re:
10/14/2003	ETH.MESH.01220710	Technical data on competitve meshes from Europe
		Email from Dan Burkley to Elizabeth Vailhe re Pore
4/22/2003	ETH.MESH.02183533	Size Request
2/8/2002	ETH.MESH.00199408	Gynemesh PS Design Validation Strategy
		Klinge U., Klosterhalfen B., Birkenhauer V., Junge
		K., Conze J., and Schumpelick V., Impact of
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2002	ETH.MESH.02232930	in a Rat Model .
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2/28/2008	ETH.MESH.02590865	presentation
		Email from Edward Dormier including the December
1/16/2001	ETH.MESH.01160507	2000 Corporate Product Characterization
	ETH.MESH.01992236	"Form for Test Method Applicability/Suitability"
1 /1 0 /2 0 0 0	DOM N. CO. C.	Email from Vincenza Zaddem to Bryan Lisa re:
1/18/2008	ETH.MESH.00906445	510(k) mesh data with strength
	ETH-01754	FDA letter stating necessary force for arm pull-out
12/15/2000	ETH MECH 000/70/0	Email attaching Viscout Leavet W. 1.
12/15/2008	ETH.MESH.00067363	Email attaching Vincent Lucente Webinar Transcript
	ETH.MESH.02227368	Meshes/Devices Chart
	ETH.MESH.02212840	Dualift Characteristics
	ETH.MESH.00081180	Prolift Characteristics Email From Christoph Welther to Vincenza Zeddem
0/10/2007	ETU MESH 021090022	Email From Christoph Walther to Vincenza Zaddem re: "Info needed for FDA"
9/10/2007	ETH.MESH.021989933	ire. This needed for FDA

		Letter from Dr. Jiyoung Dang to Bryan Lisa
8/29/2007	ETH.MESH.00080842	regarding Prolift & Prolift +M changes
0/27/2007	L111.WL511.00000042	Email from Vincenza Zaddem to Price St. Hilaire et
9/12/2007	ETH.MESH.00922443	al. regarding bidirectional elasticity statement
9/12/2007	E111.WES11.00922443	"Exploratory Program "Thunder" Powerpoint
6/18/2007	ETH MESH 01405170	
0/18/2007	ETH.MESH.01405170	presentation By: Clifford Volpe and Peter Meier
<i>5 /</i> 0/2009	ETH MESH 02227224	"MGPP Thunder Decision Meeting" powerpoint
5/9/2008	ETH.MESH.02227224	presentation
12/1/2006	ETH.MESH.02195798	Email from Axel Arnuad re Strength
6/26/2008	ETH.MESH.02195788	Prolift +M DRM
		Email from Joerg Holste re: Lightning 510(k)
3/7/2007	ETH.MESH.00078537	requirements
		Email from Jonathan Meek to Julie Bird et al. re:
10/26/2008	ETH.MESH.02207388	Prolift +M Pre-Reading
2012	ETH.MESH.03753245	"Biomechanics (Pelvic Forces) PowerPoint
		"Review of Surgical Techniques using Mesh" by
	ETH.MESH.00396836	David Robinson
		Email from Mark Yale to Jennifer Paine, Jonathan
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5/8/2008	ETH.MESH.00318775	design".
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2/16/2011	ETH.MESH.02010834	design" by Juergen Trzewik and Christoph Vailhe
2006	ETH-00255	Ethicon Marketing Brochure
		Professional Education PowerPoint presentation
		titled "The Science of Augmented Extracorporeal
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		Cobb WS, Burns JM, Peindl RD, Carbonell AM,
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		analysis of heavyweight, mid-weight, and
		lightweight polypropylene mesh in a porcine ventral
		hernia modelJ Surg Res. 2006 Nov;136(1):1-7.
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		Email from Peter Meier to Jonathan Meek, Piet
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7/13/2009	ETH.MESH.02011199	PVDF to PP
2009	ETH.MESH.01264260	Piet Hinoul Presentation
2004	ETH-65881	Gynecare Prolift IFU
2003	ETH.MESH.02053630	Gynemesh PS "White Paper"
	211111120111020000	"Prolene Resin Manufacturing Specifications" by
1/23/2003	ETH-03883	John Karl
2/28/2005	ETH-03534	DDSA Appendix II Prolift "Summary Report"
2/28/2002	ETH-03558	DDSA Appendix VI "Form" describing hazards
21 201 2002	L111-03330	Email from Martin Chomiak to Boris Batke, et al. re
7/20/2007	ETH.MESH.05920616	<u>'</u>
1/20/2007	E111.MESH.03920010	Defining light weight mesh

	ETH.MESH.01816990	Kammerer Product development chart
	ETH.MESH.05479535	Microporous, Medium & Macroporous grid
		Email from Holste to Engel et al. re: Mesh and tissue
3/13/2006	ETH.MESH.05446127	contaction in animals
		"Ethicon Polypropylene Mesh Technology"
03/2011	ETH.MESH.05479718	Powerpoint by Boris Batke
		Email from Boris Batke to Jill Schiaparelli et al. re
4/17/2003	ETH.MESH.05920530	Literature list of Lightweight Meshes
		Email from Petra Koehler to Boris Batke, et al. re Dr.
2/2/2008	ETH.MESH.05920618	Schumpelick
		Email from Boris Batke to Casey Mayes re AWES
3/1/2012	ETH.MESH.04015102	Pelvic Floor Conference - Gala Dinner invitation
6/3/2012	ETH.MESH.05585066	"Ultrapro" PowerPoint presentation by Boris Batke
		"Chronic Pain Prevention/future - Bioengineer's
	ETH.MESH.05916450	point of view"
	ETH.MESH.04037600	"Innovations in Mesh Development" By Boris Batke
		"The (clinical) argument of lightweight mesh in
	ETH.MESH.05479410	abdominal surgery" presentation by Boris Batke
		Email from Jill Schiaparelli to Karen Zaderej, Boris
5/4/2004	ETH.MESH.05918776	Batke et al. re Marlex experience
		Dynamesh, Dynamesh Light, Dynamesh IPOM:
1/13/2005	ETH.MESH.04036976	Analysis of Competitor meshes: Report
		Material Specification for TVT Prolene
	ETH.MESH.02219202	Polypropylene Mesh Roll Stock
		Email from Osman Rathore to Meng Deng et al. re
		Analytical characterization - Optimization of
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		Email from Laura Vellucci to Dennis Jamiolkowski
3/1/2012	ETH.MESH.07226377	re Polypropylene mesh
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2/29/2012	ETH.MESH.04038180	et al. re Your Professional Opinion
		Email from Piet Hinoul to Laura Vellecci et al. re
3/5/2012	ETH.MESH.04937874	Polypropylene mesh
		Response to email from Clare Huntington 26 Jnauary
		2012 (15:38) with attached publication:
		"Polypropylene as a reinforcement in pelvic surgery
		is not inert: comparative analysis of 100 explants",
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		2012 (15:38) with attached publication:
		"Polypropylene as a reinforcement in pelvic surgery
		is not inert: comparative analysis of 100 explants",
3/12/2012	ETH.MESH.07205370	Int Urogynecol J (2010) 21:261-270
		Email from Dennis Jamiolkowski to Laura Vellucci
		et al. re Information on PROLENE Suture and
3/7/2012	ETH.MESH.07226404	PROLENE Mesh
		Klosterhalfen B., Interim Report Mesh Explants
04/2008	ETH.MESH.00006636	Pelvic Floor Repair
	ETH.MESH.07726805	Burkley notes on Dr. Klinge Prolift expert report
		Seven Year Data for Ten Year Prolene Study: ERF
10/15/1992	ETH.MESH.05453719	85-219
12/14/2010	ETH.MESH.02588977	ERM team Meeting Minutes
	ETH.MESH.03699547	PA Consulting Cost
		PA Consulting "Investigating Mesh Erosion in Pelvic
5/18/2011	ETH.MESH.02589032	Floor Repair" Draft
		Email Christophe Vailhe to Joe Robinson re: Thanks
3/31/2011	ETH.MESH.07198250	& pictures
		Porosity Measurements of Various Meshes by D.F.
7/3/2002	ETH.MESH.02183537	Burkley
		Porosity Measurements of Various Meshes by D.F.
2/17/2010	ETH.MESH.05443495	Burkley
		Operating Procedure for Optical Evaluation to
		Determine Porosity of Mesh Samples Using the
		Nikon Stereomicroscope and Image-Pro Image
	ETH.MESH.05443059	Analysis System
	ETH MEGH 05 442077	AST-2010-0587 "Pore Size Measurement of Surgical
	ETH.MESH.05443077	Mesh Products"
1/2/2006	ETH MECH 00505006	Email from Gene Kammerer to Sunny Rha re TVT -
1/2/2006	ETH.MESH.00585906	TVT-O Specifications
11/14/2007	ETH.MESH.02212596	"Mesh Testing" Powerpoint presentation By Elizabeth Vailhe
11/14/2007	E1H.MESH.02212390	Enzageth vanne
		Cobb W, Kercher K, Heniford T. The Argument for
		Lightweight Polyropylene Mesh in Hernia Repair .
2005	ETH.MESH.01424029	Surgical Innovation. 2005; 12(1):T1-T7
2003	ETH.MESH.00528626	Product Quality Plan for Gyecare Gynemesh XL
	E 111.WES11.00320020	Corporate Product Characterization: Product
		Performance Evaluation Group; "Transfer of
		Finishing Operations for 6-mil Old Constructions
		Clea and 50% Blue PROLENE Mesh from
4/25/2002	ETH.MESH.01808729	ETHICON-Cornelia to PRODESCO, Inc"
7/23/2002	L 111.WILDI1.01000/29	DITTICON-Comena to I NODESCO, Inc

	ETH.MESH.05918082	"Solving the Device Design Puzzle" Powerpoint
		Corporate Product Characterization: Product
		Performance Evaluation Group; "Validation for
		Knitting, Scouring and Heat Setting 6-mil Old
		Construction Blue PROLENE Mesh at Secant
3/19/2003	ETH.MESH.01218446	Medical"
		Memo to Josh Samon from Michael Pelekis re Risk
		Assessment for Laser Cutting of D'art Gynemesh PS
4/7/2004	ETH.MESH.07190442	Implants
		Email from John Karl to Bob Washington et al. re:
8/26/2011	ETH.MESH.06261965	BraskemA Little History
		Email from Daniel Burkley to Dorothy Dion et al. re
2/3/2003	ETH.MESH.02268613	Athos: Analytical Testing
		Email from Dorothy Dion to Scott Ciarrocca re
2/21/2003	ETH.MESH.02268618	ATHOS: PROLENE Additive and Exposure
		Email from Paula Evans to Gynecare Marketing &
4/27/2005	ETH.MESH.03908707	Gynecare Umbrella re PROLENE vs. polypropylene
		Interim Report, PSE Accession NO: 05-0070 "Test
		and Control Article Material Characterization
		Program" with TVT-Secur Implant and EO
3/9/2006	ETH.MESH.00750766	Sterilization
		Email from James Flint to Elizabeth Vailhe re
4/27/2010	ETH.MESH.02185004	surface area
		TVT PROLENE Polypropylene Mesh Rool Stock
	ETH.MESH.09479067	Appendix II Digital Photograph of 050166
		Email from Joerg Holste to Judi Gauld et al. re
2/16/2011	ETH.MESH.03146492	Prosima +M clin stra
		Email from Joerg Holste to Dieter Engel re Mesh and
3/13/2006	ETH.MESH.05446127	Tissue Contraction in Animal
		"Characteristics of Synthetic Materials Used in
		Prolapse and Incontinence Surgery" powerpoint
	ETH.MESH.00838428	presentation By A. Arnaud & D. Robinson
10/2/2003	ETH.MESH.05483362	"ULTRAPRO Mesh Pricing Committee Presentation"
		Piet Hinoul Clinical Expert Report Gynecare Prolift
9/25/2012	ETH.MESH.08315779	+M Pelvic Floor Repair System
		The TVM Group, "Conceptual advances in the
11/2004	ETH.MESH.00659678	surgical management of genital prolapse" article
	ETH.MESH.05718952	Project Edelweiss Characteristics grid
		Email from Joerg Holste to Sandy Savidge re
3/11/2005	ETH.MESH.05549189	Infection Risk implantation TVT-U
		Clinical Infection Risk Assessment for Gynecare
	ETH.MESH.05505944	TVT Universal (TVT U)

		Email from Joerg Holste to Steve Bell et al. re TVT -
12/21/2004	ETH.MESH.05245392	Next Generation Questionstion
		Final Report: Ethicon Study No. SOD4/2-2-1: A 3
		month pre-clinical trial to assess the fixation force of
6/2/2005	ETH.MESH.06403725	a new TVT (TVTx) in the sheep model
		Email from Dan Smith to Allison London Brown et
1/3/2006	ETH.MESH.05246116	al. re Results of TVTx preclinical trial
	ETH.MESH.00840056	TVT - Secur PPT
		Corporate Prodcut Characterization Plan for
2/28/2006	ETH.MESH.04939027	Gynecare TVT S (Secur)
		Letter to Patrica Hojnoski from FDA re Gynecare
11/28/2005	ETH.MESH.00019925	TVT Secure System
		Preclinical Efficacy Assessment for ETHICON
7/16/2010	ETH.MESH.04940233	GYNECARE GYNEMESH M
		Email from Joerg Holste to Petra Koehler and Axel
1/20/2010	ETH.MESH.05127423	Arnaud re Tissue reaction ULTRAPRO
		Email From Christophe Vailhe to Clifford Volpe et
1/9/2012	ETH.MESH.08579092	al. Re Mesh Exposure - Ethicon Position - Short List
		Email from Christophe Vailhe to Clifford Volpe Re
2/1/2012	ETH.MESH.07200381	Exposure Position Norderstedt 2012.pptx
		"Mesh Exposure Ethicon Position" Powerpoint
2/2/2012	ETH.MESH.07200382	presentation
3/5/2012	ETH.MESH.04548236	CDMA Meeting Minutes -2012
		Letter to Michael Richter from PA Consulting re
		"Investigation into mesh erosion in pelvic floor
11/1/2010	ETH.MESH.07192033	repair"
		Email from Peter Meier to Julie Bird et al., Re Sales
2/17/2011	ETH.MESH.07192242	reps in UK
		Email from Christophe Vailhe to Ian Rhodes at PA
7/21/2011	ETH.MESH.07198825	Consulting re Mesh erosion report attached
		PA Consulting Group - Mesh Erosion Interview -
1/20/2011	ETH.MESH.07192012	Surgeon (Rhona Kearney)
		PA Consulting Group - Mesh Erosion Interview -
1/18/2011	ETH.MESH.07192412	Pathology (Klosterhalfen)
1 /1 4 /2 0 0 7	DTI 05153	Clinical Expert Report: GYNECARE PROLIFT
1/14/2005	ETH-07152	Pelvic Floor Repair System by Charlotte Owens
		Email from Christophe Vailhe to Michael Richter et
2/0/2011		al. Re: You have been selected - Forces on the pelvic
2/9/2011	ETH.MESH.07197998	floor - challenge to determine
E /10/0011	ETH MEGH 07102072	Email from Piet Hinoul to Pann Hermansson and
5/18/2011	ETH.MESH.07192872	Christophe Vailhe Re Forces in the pelvic floor
2/16/2011	ETHAREGU 00105504	Biomechanical consideration for Pelvic floor mesh
2/16/2011	ETH.MESH.02185584	design

		Email from Christophe Vailhe to Juergon Trzewik re
1/16/2012	ETH.MESH.07200224	Biomechanics of the pelvic floor
	ETH.MESH.07876572	TVT Secure 510(k)
		An exploratory 91-Day Tissue Reaction Study of
		Polypropylene Based Surgical Mesh in Parts (PSE
	ETH.MESH.01217925	ACC. NO. 00-0035)
		Holste & Barbolt signed ISO 10993 testing
8/8/2006	ETH.MESH.02091873	documents
		Email from Dan Smith to Janice Burns re Important:
2/27/2004	ETH.MESH.00863391	2 TVT complaints concerning allegedly brittle mesh
11/10/2004	ETH.MESH.02180828	Letter from Dr. Eberhard
10/18/2004	ETH.MESH.02180833	Translation of Dr. Eberhard letter
		Letter to Herve Fournier RE 810041B TVT Device,
10/12/2005	ETH.MESH.03535750	Blue Mesh - complaint
		Email from Jacqueline Flatow to Sungyoon Rha et
2/15/2006	ETH.MESH.00584291	al. Re Dver protocol for particle loss
		Email from Gene Kammerer to Herve Fourier re
5/1/2006	ETH.MESH.03358217	French Standard on TVT & Meshes
		Email from Gene Kammerer to Herve Fournier et al.
5/4/2006	ETH.MESH.01221024	Re: New Standards for Urethral Slings
		Email from Jacqueline Flatow to Gene Kammerer re
5/9/2006	ETH.MESH.01219629	Particle loss on TVT
		Email from Herve Fournier to Gene Kammerer et al.,
6/6/2006	ETH.MESH.00584488	Re: New Standards for Urethral Slings
		Email from David Robinson to Yukie Yamano et al.
8/31/2007	ETH.MESH.00844331	Re: Asking TVT Complication? - Fraying
		Email from David Robinson to Thomas Barbolt Re:
8/31/2007	ETH.MESH.00844341	Asking TVT Complications? - Fraying
		A 28-Day Intramuscular Tissue Reaction Study in
		Rats of Polyropylene Mesh from the TVT (Ulmsten)
6/18/1999	ETH.MESH.05315240	Device (PSE ACCESSION NO. 97-0197)
		Corporate Product Characterization - Product Safety
7/19/1996	ETH.MESH.04447134	Profile (Prolene)
		Biocompatbility Risk Assessment for PROLENE
10/1/1997	ETH.MESH.08218336	Polypropylene Mesh
		Literature Review on Biocompatibility of Prolene
10/1/1997	ETH.MESH.08218337	Sutures and Implants
		Mechanisms of Cytotoxicity for TVT Polypropylene
	ETH.MESH.02134271	Mesh (DRAFT)
		Histological Evaluation and Comparison of
		Mechanical Pull Out Strength of Prolene Mesh and
3/5/2003	ETH.MESH.05316755	Prolene Soft Mesh in A Rabbit Model

		Examination of an Extract of TVT-Secur Implant
		ETO Steril, Implantat for Cytotoxix Properties in a
8/8/2005	ETH.MESH.07876890	Cell Culture Test
0, 0, 0 0		Intracutaneous Test of an Extract of TVT Secur
8/8/2005	ETH.MESH.07876905	Implant ETO Steril Implantat in Rabbits
		Examination of an Eluate of TVT-Secur Implant
		ETO Steil, Implanat of Pyrogenic Properties in
8/8/2005	ETH.MESH.07876870	Rabbits
		K052401: Response to FDA's Request for Additional
	ETH.MESH.07876820	Information: Gynecare TVT Secur System
		Letter to Gregory Jones from FDA re Tension Free
1/28/1998	ETH.MESH.00371496	Vaginal Tape (TVT) System
		Biocompatibility Risk Assessment for TVT-AA -
11/2/2001	ETH.MESH.07469275	Revised
12/8/2003	ETH.MESH.00019863	TVT-O 510(k)
		Email from Mark Yale to Cindy Crosby et al. Re:
2/8/2006	ETH.MESH.00874032	MHRA Request - TVT (change to dying process)
		Biocompatibility Risk Assessment for the TVT-L
6/6/2001	ETH.MESH.01159961	Device
8/27/2008	ETH.MESH.06851860	Gynecare TVT AA - CE Mark Technical File
	ETH.MESH.02026591	Sunoco MSDS
7/9/1992	ETH.MESH.09557798	7 Year Dog Study with explant images
3/30/2012	ETH.MESH.03949361	Dyed Prolene Batch Review
10/1/1992	ETH.MESH.09557819	Handwritten notes from 7 year dog study
	ETH.MESH.00339437	5 years Sales Piece - TVT
	ETH.MESH.09671620	Weights, elasticity etc chart
	ETH.MESH.09651393	Invention disclosure
	ETH.MESH.09654601	Uniaxial Test- theoretical considerations
	ETH.MESH.03032928	FDA Review - R&D
		"Evidence to Support Innovation" PowerPoint
	ETH.MESH.02995494	presentation by Judi Gauld
12/21/2007	ETH.MESH.02588170	Slide from Trzewik presentation
		"Meshes in Pelvic Floor Repair" By Brigitte
6/6/2000	ETH.MESH.03924557	Hellhammer
	ETH.MESH.03658980	TVT-PA 510 (k)
		Email from Stephen Wolhert to Brigitte Hellhammer
7/9/2007	ETH.MESH.05588123	et al. re Costello Article
2008-2010	ETH.MESH.02340504	Gynecare TVT IFU
2006	ETH.MESH.00584491	Email re AFNOR standards
2010-Present	ETH.MESH.03427878	TVT IFU
2006-2008	ETH.MESH.05222673	TVT IFU
2005-2006	ETH.MESH.02340471	TVT IFU
2003-2005	ETH.MESH.02340306	TVT IFU

2001-	ETH.MESH.05225354	TVT IFU
	ETH.MESH.02340568	TVT-S IFU
	ETH.MESH.02340902	TVT-O IFU
	ETH-10187	Prolift Patient Brochure
	ETH.MESH.00748451	Prolif & Prolift +M 510
	ETH.MESH.02341954	Prolift & Prolift +M Patient Brochure
	ETH.MESH.00006796	Stand and Deliver PowerPoint Presentation
		Lightweight Mesh Development PowerPoint by
	ETH.MESH.04941016	Juergen Trzewik
		Email from Dieter Engel to John Gillespie et al. re
7/6/2007	ETH.MESH.05447475	How inert is polypropylene?
		"Mesh Properties - How Important are they?" by
	ETH.MESH.05237872	Peter Meier
		Pelvic Floor Repair – Surgeon's Feedback on Mesh
1999	ETH.MESH.05644163	Concept
8/4/2009	ETH.MESH.04066979	Email re Dynamesh in Brazil
		·
6/23/1998	ETH.MESH.09266657	Email from Larry Ellington re Prolene Mesh for TVT
	ETH.MESH.05225380	TVT IFU
	ETH.MESH.02340331	TVT IFU
	ETH.MESH.03427878	TVT IFU
		Gynecare TVT Secure Competitive Product Update
2007	ETH.MESH.06861473	PowerPoint presentation
7/12/2000	ETH.MESH.01317515	Preventia document
7,12,2000		Email from Axel Arnaud re Pelvic Floor Repair
8/21/2000	ETH.MESH.03909708	Procedural Strategy
0/21/2000	ZIII.WZSII.03707700	TVT Update: Success & Complications (Causes and
10/2000	ETH.MESH.04044797	recommendations)
10/2000		Scientific Advisory Panel on Pelvic Floor Repair -
6/22/2001	ETH.MESH.02089392	Preliminary Minutes
0/22/2001		Device Design Safety Assessment (DDSA) Re-
4/25/2002	ETH.MESH.01317510	Evaluation for TVT
172372002		Evaluation for 1 v 1
12/2/2005	ETH.MESH.04385229	Clinical Expert Report - Gynecare TVT Secur System
12/2/2003	ETTI.WESTI.04303227	Email from Meng Chen re TVT IFUs on tape
1/29/2009	ETH.MESH.04093125	extrusion, exposure and erosion
1/2//2007	ETH.MESH.04081189	Meeting agenda
	ETH.WESH.04001107	Email from Robin Osman re Updated Fair Balance
12/17/2008	ETH.MESH.00772231	for TVT Brochure
12/17/2008	ETH.MESH.00772228	Email from Robin Osman re 2008 Budget Spend
12/11/2000	E 111.WES11.00//2220	Email from Bryan Lisa re TVT Patient Brochure Fair
12/18/2008	ETH.MESH.00339083	Balance/EPI changes
12/10/2000	E 111.ME311.00337003	Email from Charlotte Owens re Reminder on BLUE
3/2/2004	ETH.MESH.00865322	mesh!
3/2/2004	E111.WESH.00803322	mesit:

3/9/2004	ETH.MESH.00863405	Email from Brian Luscombe re Complaint TVTO
		"The Mesh Story" PowerPoint presentation by Dan
	ETH.MESH.01805985	Smith
		Email from Joseph Lanza re Preread for Web
11/10/2009	ETH.MESH.06921060	Conference
	ETH.MESH.06696593	Design FMEA TVT LCM Project
		"Gynecare TVT Obturator System" PowerPoint
	ETH.MESH.06856958	Presentation
10/13/2002	ETH.MESH.03910183	Email from Axel Arnaud re Soft Prolene
		Email from Martin Weisberg re TVT
6/6/2001	ETH.MESH.03905472	recommendation from Dr. Alex Wang
		Email from Dan Smith re Important: 2 TVT
2/27/2004	ETH.MESH.00863391	Complaints concerning allegedly brittle mesh
11/10/2004	ETH.MESH.02180828	Dr. Eberhard Compliant
10/18/2004	ETH.MESH.02180833	Translation of Dr. Eberhard letter
5/9/2006	ETH.MESH.00585802	Email from Gene Kammerer re Particle Loss on TVT
		Email from Gene Kammerer re TVT LCM - particle
6/12/2006	ETH.MESH.00585842	loss (reimbursement submission)
	ETH.MESH.03932912	The History of TVT
		"TVT: Insights into the Making of a Revolution" by
	ETH.MESH.06859904	Sheri Dodd
11/7/2005	ETH.MESH.05220458	Email from Wanda Petire-Singer re TVT Records
		Unsigned Clinical Expert Report Gynecare TVT
	ETH.MESH.03714599	Secur System
9/15/2005	ETH.MESH.03905619	Email from Martin Weisberg re clinical expert report
11/18/2003	ETH.MESH.00541379	"Mesh fraying for TVT Devices" memo
11, 10, 2002		Email from Sandy Pompilio re Information about
10/21/2008	ETH.MESH.02310653	FDA notification on use of mesh in pelvic surgery
12/10/2004	ETH.MESH.01811770	Email from Steve Bell re VOC on Laser Cut Mesh
	ETH.MESH.06857406	"TVT-Bridge) Retaining Leadership" PPT
	ETH.MESH.01265223	Risk Managent Report (legacy) for TVT and TVT-O
		Company Procedure for Medical Device Risk
	ETH.MESH.00070187	Management Plan
		Email from Paul Parisi re TVT Laser Cut mesh
11/29/2004	ETH.MESH.01811758	business case (for meeting this afternoon)
		2010 Performance and Development Plan Summary
1/18/2011	ETH.MESH.08474562	for Daniel Smith
	ETH.MESH.01816988	Mesh Timeline
		"Characteristics of Synthetic Materials Used in
		Prolapse and Incontinence Surgery" powerpoint
	ETH.MESH.00838428	presentation By A. Arnaud & D. Robinson

		Section of Ethicon Powerpoint showing Weights
04/2008	ETH.MESH.06867612	"Matrix Material" PowerPoint Presentation
		Klinge, U., Klosterhalfen, B., Birkenhauser, V.,
		Junge, K., Conze, J., Schumpelick, V. Impact of
		Polymer Pore Size on the Interface Scar Formation
		in a Rat Model. Journal of Surgiccal Research. 103,
2002	ETH.MESH.06894461	208-214 (2002)
		"Evaluation of UltraPro Meshes" PowerPoint
	ETH.MESH.06893952	Presentation
		Email from Axel Arnaud re Mini TVT - mesh
11/26/2002	ETH.MESH.03910418	adjustment
1/16/2007	ETH.MESH.06868377	Email from Reinhard Juraschek re shrinkage review
		2007 Performance and Development Plan Summary
3/4/2008	ETH.MESH.08474542	for Daniel Smith
		Histological Evaluation and Comparison of
		Mechanical Pull Out Strength of Prolene Mesh and
2/28/2003	ETH.MESH.01222617	Prolene Soft Mesh in A Rabbit Model
	ETH.MESH.06923868	TVTO-PA Clinical Strategy
		2011 Performance and Development Plan Summary
1/20/2012	ETH.MESH.08474570	for Daniel Smith
		2008 Performance and Development Plan Summary
3/8/2009	ETH.MESH.08474547	for Daniel Smith
		2009 Performance and Development Plan Summary
1/25/2010	ETH.MESH.08474555	for Daniel Smith
		Form for Customer Requirements Specification
9/13/2010	ETH.MESH.06917699	(CRS) For Project TVT-O PA
		"TOPA & SCION PA Alignment" PowerPoint
08/2010	ETH.MESH.02218268	Presentation
		Email from Dan Smith re Update from the Oct 27
11/1/2004	ETH.MESH.05548122	cadaver
		Comparison of Laser-Cut and Machine-Cut TVT
		Mesh to Meshes from Competitive Devices (BE-
12/14/2004	ETH.MESH.01809080	2004-1641)
6/18/2008	ETH.MESH.04048515	Meeting minutes re Project Scion
	ETH.MESH.01228079	Nilsson Podcast Transcript
	ETH.MESH.02227368	Meshes/Devices Chart
		Material Specification for TVT Prolene
	ETH.MESH.02219202	Polypropylene Mesh Roll Stock
0.42.7.42.6.4.5		Piet Hinoul Clinical Expert Report Gynecare Prolift
9/25/2012	ETH.MESH.08315779	+M Pelvic Floor Repair System
		Ulmsten, U., et. Al. An Ambulatory Surgical
1004		Procedure Under Local Anesthesia for Treatment of
1996	ETH.MESH.05795664	Female Urinary Incontinence
	ETH.MESH.05972834	Asset Purchase Agreement

		Company Procedure for the Ethicon Product
	ETH.MESH.08477464	Development Process (PDP)
		20,010 1100000 (121)
		Operating Procedure for Failure Modes and Effects
	ETH.MESH.03742864	Analysis Application (AFMEA) or Design (dFMEA)
	E111.WE511.03742004	Company Procedure for Medical Device Risk
	ETH.MESH.03742571	Management Plan
	E111.WE311.03742371	Management Flan
	ETH.MESH.01268264	Risk Managent Report (legacy) for TVT and TVT-O
	ETH.MESH.03652924	Form for Internal Audit Corrective Action Plan
		Memo re TVT Laser Cut Mesh (LCM) Risk Analysis
2/24/2006	ETH.MESH.00302105	Summary
		Risk Management report TVT Laser Cut Mesh
	ETH.MESH.01310061	(LCM)
		Risk Management report TVT Laser Cut Mesh
	ETH.MESH.01310476	(LCM)
		Email from Dan Smith re TVT-O resin Minute Jan
1/29/2009	ETH.MESH.06858146	31th
1/29/2009	ETH.MESH.06858314	Test Method for the Thickness of Mesh
	E111.WES11.00030314	Work instructions for Device Design Risk
	ETH.MESH.08438961	Management
2/14/2003	ETH.MESH.06873447	Due Diligence Growth Opportunity Outline
3/4/2003	ETH.MESH.00858094	Gynecare R&D Monthly Update - March
3/4/2003	ETH.MESH.00858094 ETH.MESH.00858092	Gynecare R&D Monthly Update - March Gynecare R&D Monthly Update - June
6/24/2003		v i
0/24/2003	ETH.MESH.02180737	Email from Ronnie Toddywala re Project Mulberry
	ETH.MESH.03932909	History of TVT-O
		"Top Ten Reason To PursueGynecare TVT
		Obturator System" PowerPoint Presentation by Brian
	ETH.MESH.00857891	Luscombe
	ETH.MESH.00858891	TVT proejcts charting document
		Gyecare TVT Obturator System Sales Training
1/22/2004	ETH.MESH.00857821	Launch Meeting
		Email from Laura Angelini re Transient Leg Pain
8/8/2003	ETH.MESH.03803462	with Mulberry
12/19/2003	ETH.MESH.00259473	TVT-O DDSA
3/29/2004	ETH.MESH.02180759	Letter from Jean de Leval
7/24/2003	ETH.MESH.00864101	Email from Dan Smith re TOVT development
		Email from Julie Hocknell re Adventures with TVT
8/8/2007	ETH.MESH.06861426	Secur
8/15/2003	ETH.MESH.00864131	Email from Brian Luscombe re Aug 11 program
	ETH.MESH.03926030	Meeting minutes re Project Scion
	ETH.MESH.00858096	Gynecare R&D Monthly Update - May
5/29/2003	ETH.MESH.00260020	Study Grid

6/17/2003	ETH.MESH.01815611	Email from Dan Smith re Discussion 11th June 2003
6/3/2003	ETH.MESH.00858175	Mulberry Weekly Meeting Minutes
1/16/2004	ETH.MESH.06164409	Email from Dan Smith re Dedication
2010	ETH.MESH.06260647	R&D CO-OP Welcome Guide Spring 2010
	ETH.MESH.01316727	Design History 1 book 1999 - TVT 5mm version
	ETH.MESH.01317508	Design History 1 book 1998 - TVT factbook
		TVT Classic IFU Revision Project Design
11/19/2010	ETH.MESH.00748213	Requirements Waiver Rationale Memo
	ETH.MESH.00858636	TVT Secur lessons learned review
		Corporate Product Characterization plan for
7/18/2005	ETH.MESH.04939148	Gynecare TVT S (Secur)
	ETH.MESH.01150009	Gynecare TVT Secur Presentation by Dan Smith
2007	ETH.MESH.06861473	Gynecare TVT Secur Competitive Product Update
	ETH.MESH.06860553	TVT & TVT Secur Documents
		Company Procedure for the Ethicon Product (PDP) -
	ETH.MESH.04316544	Design Controls
		Company Procedure for Design Changes to Existing
	ETH.MESH.00363605	Products
		Operating Procedure for Failure Modes and Effects
	ETH.MESH.05432198	Analysis Application (AFMEA) or Design (dFMEA)
		Email from Dan Smith to TVTx - Next Generation
10/7/2004	ETH.MESH.05456924	TVT "Project Initiation"
11/22/2004	ETH.MESH.00259042	2004 Strategy Tree Project Definition
	ETH.MESH.01217673	TVT-NEXT (TVTx) Development contract
		Email from Raimo Sump re TVT Secur Minutes -
4/25/2005	ETH.MESH.06274935	Team Meeting April 12 2005
	ETH.MESH.01410044	Gynecare TVT Secur Product Specs and changes
	ETH.MESH.05554367	Finger Pad Detail Drawings
	ETH.MESH.04385192	Gynecare TVT Secur Product Specs and changes
	ETH.MESH.05502894	Design Requirements Matrix - TVT S
	ETH.MESH.01592178	Design Validation Report - TVT S
	ETH.MESH.07876572	TVT Secure 510(k)
	ETH.MESH.02135955	Design Validation Report - TVT S
		Email from Kevin Mahar re TVT O versus TVT
10/29/2007	ETH.MESH.00642325	Secur efficacy and safety rate
7/28/2004	ETH.MESH.06869750	Human Cadaver Wetlab
		A 3 month pre-clinical trial to assess the fixation
		force of a new TVT (TVTx) in the sheep model -
2/8/2005	ETH.MESH.01037530	Ethicon's Final Report
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2/19/2004	ETH.MESH.06892171	COMMENTS!!!!!!!
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7/21/2004	ETH.MESH.03910799	Email from Axel Arnaud re TVT Erosions?
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1/8/2007	ETH.MESH.03912639	Email from Axel Arnaud re TVT Cookbooks
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11/11/1998	ETH.MESH.10182005	Meeting minutes of Project Planning Meeting
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1 /1 0 /2 0 0 2		Ethicon Surgeon Panel Meeting - Mesh - Suvretta
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Date	Deponent
02/28/2012	
02/29/2012	Cliff Volpe
04/05/2012	_
04/06/2012	
09/18/2012	
06/29/2013	
06/27/2013	Piet Hinoul
03/13/2012	
03/14/2012	
08/23/2012	
09/11/2013	David Robinson
3/9/2012	Sunny Rha
4/18/2012	Aaron Kirkemo
5/18/2012	Sean O'Bryan
03/29/2012	
03/30/2012	
12/03/2012	Scott Ciarrocca
03/27/2012	
03/28/2012	Vincenza Zaddem
2/24/2012	Elizabeth Vailhe
06/20/2013	
06/21/2013	Christophe Vailhe
12/14/2012	
12/15/2012	
07/29/2013	
07/30/2013	Joerg Holste
08/01/2013	
08/02/2013	Boris Batke
10/02/2012	
05/22/2013	
05/23/2013	Daniel Burkley

10/09/2012	
10/10/2012	
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01/07/2014	
01/08/2014	Thomas Barbolt
09/11/2013	
09/12/2013	Brigitte Hellhammer
09/18/2013	
09/19/2013	Juergen Trzewik
5/31/2013	Martin Weisberg
7/20/13	
9/25/2013	Axel Arnaud
05/15/2013	
05/16/2013	
06/04/2013	
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08/20/2013	
08/21/2013	Dan Smith
01/13/2014	
01/14/2014	
01/15/2014	Piet Hinoul
3/26/2014	
3/27/2014	Trial Testimony of Piet
3/28/2014	Hinoul

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EXPERT REPORTS:

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Expert Report of Dr. Daniel
Elliott, MD